

CORTEX PHARMACEUTICALS INC/DE/
Form S-3/A
March 02, 2004
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As Filed with the Securities and Exchange Commission on March 2, 2004

Registration No. 333-112043

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO
FORM S-3
REGISTRATION STATEMENT
Under
THE SECURITIES ACT OF 1933

CORTEX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation or organization)

33-0303583
(I.R.S. Employer Identification No.)

15241 Barranca Parkway, Irvine, California 92618

(949) 727-3157

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

Roger G. Stoll, Ph.D.

President and Chief Executive Officer

Cortex Pharmaceuticals, Inc.

15241 Barranca Parkway

Irvine, California 92618

(949) 727-3157

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

Copy to:

Lawrence B. Cohn, Esq.

Stradling Yocca Carlson & Rauth,

A Professional Corporation

660 Newport Center Drive, Suite 1600

Newport Beach, California 92660

Approximate date of commencement of proposed sale to public: From time to time after the effective date of this Registration Statement.

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

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

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

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

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

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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SUBJECT TO COMPLETION, DATED MARCH 2, 2004

PROSPECTUS

CORTEX PHARMACEUTICALS, INC.

11,743,710 Shares of Common Stock

(\$0.001 par value)

This prospectus relates to the offer and sale from time to time of up to 6,909,091 shares of our outstanding common stock, and up to 4,834,619 shares of our common stock issuable upon the exercise of warrants, which are held by certain stockholders and warrant holders named in this prospectus.

The prices at which such stockholders and warrant holders may sell the shares in this offering will be determined by the prevailing market price for the shares or in negotiated transactions. We will not receive any of the proceeds from the sale of the shares.

Our common stock is traded on The American Stock Exchange under the symbol COR. On March 1, 2004, the last reported sale price of our common stock was \$2.98 per share.

See Risk Factors beginning on page 3 to read about the risks you should consider carefully before buying shares of our common stock.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement containing this prospectus, which was filed with the Securities and Exchange Commission, is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this Prospectus is _____, 2004.

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You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. Offers to sell and offers to buy the shares of common stock are valid only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as to the date of this prospectus, regardless of the time of delivery of the prospectus or of any sale of the common stock.

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ABOUT CORTEX PHARMACEUTICALS

In this prospectus, the terms Cortex, the Company, we, us, and our refer to Cortex Pharmaceuticals, Inc.

Cortex is engaged in the discovery and development of innovative pharmaceuticals for the treatment of neurodegenerative diseases and other neurological and psychiatric disorders. Since 1993, our primary efforts have been to develop products that affect the AMPA-type glutamate receptor, a complex of proteins that is involved in communication between nerve cells in the human brain. We are developing a family of chemical compounds, known as AMPAKINE[®] compounds, that enhance the activity of this receptor. We believe that AMPAKINE compounds hold promise for correcting deficits brought on by a variety of diseases and disorders that are known, or thought, to involve depressed functioning of pathways in the brain that use glutamate as a neurotransmitter.

The AMPAKINE program addresses large potential markets. Our commercial development plan involves partnering with larger pharmaceutical companies for research, development, clinical testing, manufacturing and global marketing of AMPAKINE products for those indications that require sizable, expensive clinical trials and very large sales forces to achieve significant market penetration. At the same time, we plan to develop internally a selected set of indications, eligible for Orphan Drug status. These indications typically require more modest investment in the development stages, and involve a more concentrated sales force to reach selected medical centers and a limited number of medical specialists in the United States. If we are successful in the pursuit of this operating strategy, we may be in a position to contain our costs over the next few years, to maintain our focus on the research and early development of novel pharmaceuticals (where we believe that we have the ability to compete) and eventually to participate more fully in the commercial development of AMPAKINE products in the United States.

We currently have an exclusive license agreement with NV Organon (Organon), a subsidiary of Akzo Nobel under which Organon has worldwide rights to develop and commercialize our AMPAKINE technology for the treatment of schizophrenia and depression. We also have a research collaboration and license agreement with Les Laboratoires Servier (Servier) which allows Servier to develop and commercialize our AMPAKINE technology in defined territories of Europe, Asia, the Middle East and certain South American countries as a treatment for memory impairment associated with aging and neurodegenerative diseases. The indications covered include, but are not limited to, Alzheimer's disease, Mild Cognitive Impairment, sexual dysfunction, anxiety disorders and the dementia associated with multiple sclerosis and Amyotrophic Lateral Sclerosis.

Independently we are investigating the applicability of AMPAKINE compounds to treatment of fragile X syndrome, autism, narcolepsy and the effects of sleep deprivation.

We continue to seek collaborative or licensing arrangements with other pharmaceutical companies for large market opportunities and to investigate opportunities for our direct commercialization of smaller market opportunities.

We are a development stage company and face a number of risks in moving our technology through research, development and commercialization. Since our inception in 1987, we have never had revenues from commercial sales, have never been profitable on an annual basis and have incurred net losses approximating \$45,863,000. We do not anticipate profitability in the short term and will continue to require external funding, either from the private or public equity markets or from corporate partners and licensees of our technology. Even if we obtain sufficient funding, the

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pharmaceutical development and approval process is protracted and often the new drug candidates of companies such as ours fail in clinical trials. Even after approval, the success of a new drug is dependent on patient, physician and payor acceptance. Further, at any stage, our competitors may develop and market superior drugs or assert intellectual property rights which impair our ability to commercialize our drugs. As of yet, we have not obtained FDA approval to market any of our products. All of these risks, and others, are described in Risk Factors starting on page 3.

More comprehensive information about us is available through our World Wide Web site at <http://www.cortexpharm.com>. The information on our website is not incorporated by reference into this prospectus. Our executive offices are located at 15241 Barranca Parkway, Irvine, California 92618, and our telephone number is (949) 727-3157.

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RISK FACTORS

Your investment in our common stock involves a high degree of risk. You should consider the risks described below and the other information contained in this prospectus and incorporated by reference in this prospectus carefully before deciding to invest in our common stock. If any of the following risks actually occur, our business, financial condition and operating results would be harmed. As a result, the trading price of our common stock could decline, and you could lose a part or all of your investment.

Risks related to our business

We have a history of net losses; we expect to continue to incur net losses and we may never achieve or maintain profitability.

Since our formation on February 10, 1987 through December 31, 2003, we have generated only modest operating revenues and we have incurred net losses approximating \$45,863,000. For the fiscal years ended June 30, 2001, 2002 and 2003, and the six-month period ended December 31, 2003, our net losses amounted to \$2,673,000, \$983,000, \$1,175,000, and \$3,806,000, respectively. As of December 31, 2003, we had an accumulated deficit of approximately \$47,895,000. We have not generated any revenue from product sales to date, and it is possible that we will never generate revenues from product sales in the future. Even if we do achieve significant revenues from product sales, we expect to incur significant operating losses over the next several years. It is possible that we will never achieve profitable operations.

We will need additional capital in the future and, if it is not available on terms acceptable to us, or at all, we may need to scale back our research and development efforts and may be unable to continue our business operations.

We will require substantial additional funds to advance our research and development programs and continue our operations, particularly if we decide to independently conduct later-stage clinical testing and apply for regulatory approval of any of our proposed products. Based on our current operating plan, including planned clinical trials and other product research and development costs, we estimate that our existing cash resources, including committed sources of funding from Servier, will be sufficient to meet our requirements through calendar year 2006. However, we believe that we will require additional capital to fund on-going operations beyond that time. Additional funds may result from milestone payments related to our agreements with Organon and Servier, although there is no assurance that we will receive milestone payments from Organon or Servier within the desired timeframe, or at all.

Our cash requirements in the future may be significantly different from our current estimates and depend on many factors, including:

the results of our clinical trials;

the time and costs involved in obtaining regulatory approvals;

the ability to obtain funding under contractual and licensing agreements;

the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property; and
our success in entering into collaborative relationships with other parties.

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To finance our future activities, we may seek funds through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We cannot say with any certainty that we will be able to obtain the additional needed funds on reasonable terms, or at all. The sale of additional equity or convertible debt securities could result in additional dilution to our stockholders. If we issued preferred equity or debt securities, these securities could have rights superior to holders of our common stock, and could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products that we otherwise would not relinquish. If adequate funds are not available, we could lose our key employees and might have to delay, scale back or eliminate one or more of our research and development programs, which would impair our future prospects. In addition, we may be unable to meet our research spending obligations under our existing licensing agreements and may be unable to continue our business operations.

Our products rely on licenses from the Regents of the University of California, and if we lose access to these technologies, our business would be substantially impaired.

Under our agreements with the Regents of the University of California, we have exclusive rights to AMPAKINE[®] compounds for all applications for which the University has patent rights, other than endocrine modulation, and the treatment of sexual dysfunction in North and South America.

Our rights to the AMPAKINE compounds are secured by patents or patent applications owned wholly by the University or by the University as a co-owner with us. Our existing agreements with the University require the University to prepare, file, prosecute and maintain patent applications related to our licensed rights at our expense. Such agreements also require us to make certain minimum annual payments, meet certain milestones or diligently seek to commercialize the underlying technology.

Under our agreements, we are required to make minimum annual royalty payments approximating \$75,000. Separately, we are required to spend a minimum of \$750,000 per year to advance the AMPAKINE compounds during the three years ending in May 2006. At the end of May 2006, our spending requirements will decrease to \$250,000 per year, and will continue at that level until we begin marketing an AMPAKINE compound.

The commercialization efforts in the agreements require us to initiate human clinical testing of an AMPAKINE compound, other than CX516, by July 2005, and to file for regulatory approval of an AMPAKINE compound during October 2007. Although we currently are in compliance with our obligations under the agreements, including minimum annual payments and diligence milestones, our failure to meet any of these requirements could allow the University to terminate that particular agreement. We believe our relationship with the University is good.

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We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies.

The development of AMPAKINE products is subject to the risks of failure commonly experienced in the development of products based upon innovative technologies and the expense and difficulty of obtaining approvals from regulatory agencies. Drug discovery and development is time consuming, expensive and unpredictable. On average, only one out of many thousands of chemical compounds discovered by researchers proves to be both medically effective and safe enough to become an approved medicine. Additionally, according to MedAd News, only one compound in the pharmaceutical industry generally reaches the market for every 13 discovered and placed in preclinical trials. In the fields that we target, approximately one in five compounds placed in clinical trials generally reaches the market. All of our proposed products are in the preclinical or early clinical stage of development and will require significant additional funding for research, development and clinical testing before we are able to submit them to any of the regulatory agencies for clearances for commercial use. Our AMPAKINE compound, CX516, has undergone considerable clinical trials, some of which are continuing. This compound has a short half-life and is weaker than our newer AMPAKINE compounds and we have concluded that we will not further develop CX516, although we may be required to complete and report on some of the ongoing clinical trials on that compound.

The process from discovery to development to regulatory approval can take several years and drug candidates can fail at any stage of the process. Late stage clinical trials often fail to replicate results achieved in earlier studies. Historically, in our industry more than half of all compounds in development failed during Phase II trials and 30% failed during Phase III trials. We cannot assure you that we will be able to complete successfully any of our research and development activities. Even if we do complete them, we may not be able to market successfully any of the products or be able to obtain the necessary regulatory approvals or assure that healthcare providers and payors will accept our products. We also face the risk that any or all of our products will not work as intended or that they will be unsafe, or that, even if they do work and are safe, that our products will be uneconomical to manufacture and market on a large scale. Due to the extended testing and regulatory review process required before we can obtain marketing clearance, we do not expect to be able to commercialize any therapeutic drug for several years, either directly or through our corporate partners or licensees.

A significant percentage of our revenues come from our agreements with Organon and Servier, and if either or both agreements were terminated, our revenues could be impaired.

We are dependent on future payments from Organon and Servier to continue the development and commercialization of our AMPAKINE technology for the relative sub-licensed indications. Under the agreement with Organon that we entered in January 1999, the collaborative research phase ended in January 2001. Organon has primary responsibility for developing and commercializing AMPAKINE compounds for use in the treatment of schizophrenia and depression. Through December 31, 2003 we have received \$8,000,000 in up-front and milestone payments and approximately \$6,000,000 in research support payments. The agreement includes additional milestone payments, plus royalty payments on products sold, if any, on a worldwide basis. Under the terms of the agreement, Organon has the right to terminate the agreement upon four-months prior notice. Such termination may have negative effects on our stock price and could impact our ability to achieve other licensing arrangements on acceptable terms, or at all.

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Under the agreement with Servier that we entered into in October 2000, as amended to date, we share the research efforts. Servier has primary responsibility for developing and commercializing AMPAKINE compounds for use in the treatment of memory impairment associated with aging, and of neurodegenerative diseases such as Alzheimer's disease. Through December 31, 2003, we have received an up-front payment of \$5,000,000 and research support payments of approximately \$8,700,000. Under the October 2000 agreement, as amended to date, we currently receive approximately \$2,115,000 per year (subject to us providing agreed-upon levels of research) and Servier is obligated to continue this level of support until early December 2005. Under the October 2002 amendment, we currently receive an additional \$2,000,000 per year, which Servier is obligated to continue until October 2004. The agreement includes milestone payments, plus royalty payments on product sales, if any, in licensed territories. We do not anticipate that we will receive any milestone payments from Servier during the fiscal year ending June 30, 2004. Under the terms of the agreement, Servier has the right to terminate the agreement in the case of a merger or acquisition involving us and a third party. Servier also has the right to terminate the agreement upon six-months' prior notice at any time after the research phase of the collaboration. In addition, Servier has the right to terminate the related research and development in the event that we materially breach the agreement.

As described above, each of our agreements with Organon and Servier provides us with the opportunity to receive future milestone payments upon the achievement of certain milestones. In the event that all of the milestones set forth in such agreements are met, we estimate that we could collectively receive up to an additional aggregate of \$30,000,000 in future milestone payments. However, we cannot assure you that we will be able to meet all or any of the specified milestones, in which case we would not receive the corresponding future milestone payments.

We may not be able to enter into the strategic alliances necessary to fully develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.

In addition to our agreements with Organon and Servier, we are seeking other pharmaceutical company partners to develop other major indications for the AMPAKINE compounds. These agreements would potentially provide us with additional funds in exchange for exclusive or non-exclusive license or other rights to the technologies and products that we are currently developing. Competition between biopharmaceutical companies for these types of arrangements is intense. Although we have been engaged in discussions with candidate companies for some time, we cannot give any assurance that these discussions will result in an agreement or agreements in a timely manner, or at all. Additionally, we cannot assure you that any resulting agreement will generate sufficient revenues to offset our operating expenses and longer-term funding requirements.

In connection with our efforts to secure corporate partners, we will seek to retain certain co-promotional rights to our proposed products. These co-promotional rights will allow us to market our products to selected medical specialists while our corporate partner markets our products to the general medical market. We cannot assure you that we will be able to enter into any partnering arrangements on this or any other basis. In addition, we cannot assure you that we, Organon, Servier or our prospective corporate partners, can successfully introduce our proposed products. We also face the risks that our products will be rejected by patients, health care providers or insurance companies, or that our products cannot be manufactured and marketed at prices that would permit us to operate profitably. Additionally, we plan to develop certain compounds for selected smaller indications referred to previously as Orphan Drugs. We may or may not be successful in getting the appropriate clinical results and obtaining approval to market our compounds for these indications in the United States.

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If we are unable to maintain our relationships with academic consultants and the University of California, Irvine, our business could suffer.

We depend upon our relationships with academic consultants, particularly Dr. Gary S. Lynch of the University of California, Irvine. Dr. Lynch plays a key role in guiding our research. In addition, we sponsor preclinical research in Dr. Lynch's laboratories at the University of California, Irvine that is part of our product development and corporate partnering profile. If our relationship with Dr. Lynch or the University of California, Irvine, is disrupted, our AMPA-receptor research program could be adversely affected. The term of our consulting agreement with Dr. Lynch commenced in November 1987 and will continue until terminated by either party to the agreement upon at least 60 days' prior written notice to the other party. Our agreements with our other consultants are generally also terminable by the consultant on short notice.

Risks related to our industry

If we fail to secure adequate intellectual property protection, it could significantly harm our financial results and ability to compete.

Our success will depend, in part, on our ability to get patent protection for our products and processes in the United States and elsewhere. We have filed and intend to continue to file patent applications as we need them. However, additional patents that may issue from any of these applications may not be sufficiently broad to protect our technology. Also, any patents issued to us or licensed by us may be challenged by others, and if successful, such challenges may diminish our rights.

If we are unable to obtain sufficient protection of our proprietary rights in our products or processes prior to or after obtaining regulatory clearances, our competitors may be able to obtain regulatory clearance and market competing products by demonstrating the equivalency of their products to our products. If they are successful at demonstrating the equivalency between the products, our competitors would not have to conduct the same lengthy clinical tests that we have conducted.

We also rely on trade secrets and confidential information that we try to protect by entering into confidentiality agreements with other parties. Those confidentiality agreements may be breached, and our remedies may be insufficient to protect the confidential information. Further, our competitors may independently learn our trade secrets or develop similar or superior technologies. To the extent that our consultants, key employees or others apply technological information independently developed by them or by others to our projects, disputes may arise regarding the proprietary rights to such information. We cannot assure you that such disputes will be resolved in our favor.

We may be subject to potential product liability claims. One or more successful claims brought against us could materially impact our business and financial condition.

The clinical testing, manufacturing and marketing of our products may expose us to product liability claims. We maintain liability insurance with coverage limits of \$5 million per occurrence and \$5 million in the annual aggregate. We have never been subject to a product liability claim, and we require each patient in our clinical trials to sign an informed consent agreement that describes the

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risks related to the trials, but we cannot assure you that the coverage limits of our insurance policies will be adequate or that one or more successful claims brought against us would not have a material adverse effect on our business, financial condition and result of operations. Further, if one of our AMPAKINE compounds is approved by the FDA for marketing, we cannot assure you that adequate product liability insurance will be available, or if available, that it will be available at a reasonable cost. Any adverse outcome resulting from a product liability claim could have a material adverse effect on our business, financial condition and results of operations.

We face intense competition that could result in products that are superior to the products that we are developing.

Our business is characterized by intensive research efforts. Our competitors include many companies, research institutes and universities that are working in a number of pharmaceutical or biotechnology disciplines to develop therapeutic products similar to those we are currently investigating. For example, the Pharmaceutical Research and Manufacturers of America estimates that more than 100 pharmaceutical and biotechnology companies are conducting research in the field of neurological disorders, with over 25 drugs under clinical investigation in the United States for the treatment of Alzheimer's disease. Virtually all of the major multinational pharmaceutical companies have active projects in these areas. Most of these competitors have substantially greater financial, technical, manufacturing, marketing, distribution and/or other resources than we do. In addition, many of our competitors have experience in performing human clinical trials of new or improved therapeutic products and obtaining approvals from the FDA and other regulatory agencies. We have no experience in conducting and managing later-stage clinical testing or in preparing applications necessary to obtain regulatory approvals. Accordingly, it is possible that our competitors may succeed in developing products that are safer or more effective than those that we are developing and may obtain FDA approvals for their products faster than we can. We expect that competition in this field will continue to intensify.

We may be unable to recruit and retain our senior management and other key technical personnel on whom we are dependent.

We are highly dependent upon key management and technical personnel and currently do not carry any insurance policies on such persons. In particular, we are highly dependent on our Chairman, President and Chief Executive Officer, Roger G. Stoll, Ph.D., and our Senior Vice President, Pharmaceutical Research, Gary A. Rogers, Ph.D., both of whom have entered into employment agreements with us. Competition for qualified employees among pharmaceutical and biotechnology companies is intense. The loss of any of our key management or technical personnel, or our inability to attract, retain and motivate the additional highly-skilled employees and consultants that our business requires, could substantially hurt our business and prospects. We cannot assure you that we will be able to retain our existing personnel or attract additional qualified employees when we need them.

The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining required approvals for the commercialization of some of our products.

The FDA and other similar agencies in foreign countries have substantial requirements for therapeutic products. Such requirements often involve lengthy and detailed laboratory, clinical and post-clinical testing procedures and are expensive to complete. It often takes companies many years to satisfy these requirements, depending on the complexity and novelty of the product. The review process is also extensive, which may delay the approval process even more. According to the

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Pharmaceutical Research and Manufacturers of America, historically the cost of developing a new pharmaceutical from discovery to approval was approximately \$800 million, and this amount is expected to increase annually.

As of yet, we have not obtained any approvals to market our products. Further, we cannot assure you that the FDA or other regulatory agency will grant us approval for any of our products on a timely basis, if at all. Even if regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems may result in restrictions on marketing or withdrawal of the product from the market.

Risks related to this offering

Our stock price may be volatile and our common stock could decline in value.

The market price of securities of life sciences companies in general has been very unpredictable. The range of sales prices of our common stock for fiscal years ended June 30, 2003 and June 30, 2002, as quoted on The American Stock Exchange, was \$0.51 to \$2.49 and \$1.50 to \$3.44, respectively. The following factors, in addition to factors that affect that market generally, could significantly impact our business, and the market price of our common stock could decline:

- competitors announcing technological innovations or new commercial products;
- competitors' publicity regarding actual or potential products under development;
- regulatory developments in the United States and foreign countries;
- developments concerning proprietary rights, including patent litigation; and
- public concern over the safety of therapeutic products.

There is a large number of shares of common stock that may be sold, which may depress the market price of our stock.

Upon effectiveness of the registration statement of which this prospectus is a part, an additional 6,909,091 shares will become freely tradable without restriction. If all outstanding warrants and options are exercised prior to their expiration, approximately 13.1 million additional shares of common stock could become freely tradable without restriction. Sales of substantial amounts of common stock in the public market could adversely affect the prevailing market price of our common stock.

Our charter document and shareholder rights plan may prevent or delay an attempt by our stockholders to replace or remove management.

Certain provisions of our restated certificate of incorporation, as amended, could make it more difficult for a third party to acquire control of our business, even if such change in control would be beneficial to our stockholders. Our restated certificate of incorporation, as amended, allows our Board of Directors to issue up to 549,500 shares of preferred stock without stockholder approval. Pursuant to this authority, in February 2002 our Board of Directors adopted a shareholder rights plan and declared a dividend of a right to purchase one one-thousandth of a share of preferred stock for each outstanding share of our common stock. The ability of our Board of Directors to issue additional preferred stock and our shareholder rights plan may have the effect of delaying or preventing an attempt by our stockholders to replace or remove existing directors and

management.

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FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference into this prospectus contain forward-looking statements that are based on current expectations, estimates and projections about our industry, management's beliefs, and assumptions made by management. Words such as anticipates, expects, intends, plans, believes, seeks, estimates, and variations of such words and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict; therefore, actual results may differ materially from those expressed or forecasted in any forward-looking statements. The risks and uncertainties include those noted in "Risk Factors" below and in the documents incorporated by reference. We undertake no duty to update any of these forward-looking statements.

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USE OF PROCEEDS

The proceeds from the sale of each selling stockholder's and warrant holder's common stock will belong to that selling stockholder or warrant holder, as the case may be. We will not receive any proceeds from such sales.

We may receive proceeds from the exercise of warrants held by the selling warrant holders. We plan to use these proceeds, if any, for working capital purposes. Specifically, we plan to use the potential proceeds to accelerate the development of our second generation AMPAKINE compounds. That development involves performing toxicology and other required safety testing before we advance the compounds into human clinical testing.

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We issued 6,909,091 shares of common stock and warrants to purchase an additional 4,490,910 shares of common stock on January 7, 2004 in a private placement to certain stockholders who are accredited investors. Pursuant to a Registration Rights Agreement dated January 7, 2004, we agreed to file a registration statement, of which this prospectus is a part, with the Securities and Exchange Commission to register the resale of the shares of our common stock we issued, and which we will issue upon exercise of warrants, to those stockholders and to keep the registration statement effective until the date when all of the shares registered hereunder are sold or the date on which the shares registered hereunder can be sold without registration and without restriction as to the number of shares that may be sold.

In addition, between October 1, 2003 and January 15, 2004 we issued warrants to purchase 343,709 shares of common stock, including warrants to purchase 327,709 shares of common stock to placement agents in connection with the aforementioned private placement. Under each of these warrants we are required to include the shares underlying those warrants in the registration statement of which this prospectus is a part.

None of the selling stockholders or warrant holders have any position, office or material relationship with the Company.

The following table sets forth: (1) the name of each of the selling stockholders or warrant holders for whom we are registering the resale of shares under this registration statement; (2) the number of shares of our common stock owned by each such selling stockholder or warrant holder prior to this offering; (3) the number of shares of our common stock being offered pursuant to this prospectus; and (4) the number of shares, and (if one percent or more) the percentage of the total of the outstanding shares, of our common stock to be owned by each such selling stockholder or warrant holder after this offering.

| Name | Common Stock Owned Prior to the Offering | Common Stock Being Offered Pursuant to this Prospectus | Common Stock Owned Upon Completion of this Offering | Percentage of Common Stock Owned Upon Completion of this Offering |
|---|---|---|--|--|
| Accipiter Life Sciences Fund, LP ⁽¹⁾ | 351,849 | 351,849 | 0 | 0 |
| Accipiter Life Sciences Fund (QP), LP ⁽²⁾ | 215,310 | 215,310 | 0 | 0 |
| Accipiter Life Sciences Fund, Ltd. ⁽³⁾ | 332,841 | 332,841 | 0 | 0 |
| Alexandra Global Master Fund, Ltd. ⁽⁴⁾ | 165,000 | 165,000 | 0 | 0 |
| Basso Multi-Strategy Holding Fund Ltd. ⁽⁵⁾ | 82,500 | 82,500 | 0 | 0 |
| Basso Equity Opportunity Holding Fund Ltd. ⁽⁶⁾ | 215,834 | 82,500 | 133,334 | * |

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| Name | Common Stock Owned Prior to the Offering | Common Stock Being Offered Pursuant to this Prospectus | Common Stock Owned Upon Completion of this Offering | Percentage of Common Stock Owned Upon Completion of this Offering |
|--|---|---|--|--|
| Michael R. Hamblett ⁽⁷⁾ | 60,001 | 60,001 | 0 | 0 |
| SRG Capital LLC ⁽⁸⁾ | 90,001 | 90,001 | 0 | 0 |
| Benjamin Partners Inc. Savings Plan F/B/O Jeffrey Benison ⁽⁹⁾ | 46,200 | 46,200 | 0 | 0 |
| Bristol Investment Fund, Ltd. ⁽¹⁰⁾ | 210,001 | 210,001 | 0 | 0 |
| Steve Kovacs Investments Ltd. ⁽⁵⁾ | 82,500 | 82,500 | 0 | 0 |
| Stonestreet LP ⁽⁴⁾ | 165,000 | 165,000 | 0 | 0 |
| CC LifeScience, Ltd. ⁽¹¹⁾⁽⁴⁵⁾ | 480,000 | 480,000 | 0 | 0 |
| Castle Creek Healthcare Partners LLC ⁽¹²⁾⁽⁴⁵⁾ | 433,334 | 300,000 | 133,334 | * |
| Cranshire Capital, L.P. ⁽¹³⁾ | 799,999 | 599,999 | 200,000 | * |
| Crescent International Ltd. ⁽¹⁴⁾ | 198,000 | 198,000 | 0 | 0 |
| DKR Saturn Holding Fund Ltd. ⁽¹⁵⁾ | 54,945 | 54,945 | 0 | 0 |
| DKR Saturn Event Driven Holding Fund Ltd. ⁽¹⁶⁾ | 275,055 | 275,055 | 0 | 0 |
| Elliott Associates, L.P. ⁽¹⁷⁾ | 67,000 | 66,000 | 1,000 | * |
| Elliott International, L.P. ⁽¹⁸⁾ | 100,000 | 99,000 | 1,000 | * |
| Capital Ventures International ⁽¹⁹⁾⁽⁴⁵⁾ | 600,000 | 600,000 | 0 | 0 |
| Langley Partners, L.P. ⁽²⁰⁾ | 520,000 | 360,000 | 160,000 | * |
| Omicron Master Trust ⁽²¹⁾ | 496,667 | 330,000 | 166,667 | * |
| Perceptive Life Science Master Fund, Ltd. ⁽²²⁾ | 990,000 | 990,000 | 0 | 0 |
| Portside Growth and Opportunity Fund ⁽²³⁾⁽⁴⁵⁾ | 433,333 | 300,000 | 133,333 | * |
| Quogue Capital LLC ⁽²⁴⁾ | 214,500 | 214,500 | 0 | 0 |
| RHP Master Fund, Ltd. ⁽²⁵⁾ | 150,000 | 150,000 | 0 | 0 |
| R&R Opportunity Fund LP ⁽²⁶⁾ | 52,198 | 52,198 | 0 | 0 |
| Sands Brothers Venture Capital Fund LLC ⁽²⁷⁾⁽⁴⁵⁾ | 60,000 | 60,000 | 0 | 0 |
| Sands Brothers Venture Capital Fund II LLC ⁽²⁷⁾⁽⁴⁵⁾ | 60,000 | 60,000 | 0 | 0 |

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| Name | Common Stock Owned Prior to the Offering | Common Stock Being Offered Pursuant to this Prospectus | Common Stock Owned Upon Completion of this Offering | Percentage of Common Stock Owned Upon Completion of this Offering |
|---|---|---|---|---|
| Sands Brothers Venture Capital Fund III LLC ⁽²⁸⁾⁽⁴⁵⁾ | 300,000 | 300,000 | 0 | 0 |
| Sands Brothers Venture Capital Fund IV LLC ⁽²⁹⁾⁽⁴⁵⁾ | 120,000 | 120,000 | 0 | 0 |
| SB Opportunity Technology Associates ⁽³⁰⁾⁽⁴⁵⁾ | 30,000 | 30,000 | 0 | 0 |
| Katie & Adam Bridge Partners LP ⁽³⁰⁾⁽⁴⁵⁾ | 30,000 | 30,000 | 0 | 0 |
| Satellite Asset Management LP ⁽²⁸⁾ | 300,000 | 300,000 | 0 | 0 |
| SF Capital Partners Ltd. ⁽³¹⁾⁽⁴⁵⁾ | 330,000 | 330,000 | 0 | 0 |
| Smithfield Fiduciary, LLC ⁽³²⁾⁽⁴⁵⁾ | 564,968 | 300,001 | 264,967 | * |
| TCMP3 Partners ⁽³³⁾ | 89,100 | 89,100 | 0 | 0 |
| The Tail Wind Fund Limited ⁽³⁴⁾ | 500,000 | 300,000 | 200,000 | * |
| Topaz Partners ⁽²⁸⁾⁽⁴⁵⁾ | 300,000 | 300,000 | 0 | 0 |
| Ursus Capital LP ⁽³⁵⁾ | 146,025 | 146,025 | 0 | 0 |
| Ursus Offshore Ltd. ⁽³⁶⁾ | 101,475 | 101,475 | 0 | 0 |
| Viking Global Equities LP ⁽³⁷⁾ | 834,900 | 834,900 | 35,400 | * |
| VGE III Portfolio Ltd. ⁽³⁸⁾ | 815,100 | 815,100 | 34,200 | * |
| Xmark Fund, L.P. ⁽³⁹⁾ | 191,440 | 124,773 | 78,124 | * |
| Xmark Fund, Ltd. ⁽⁴⁰⁾ | 338,560 | 205,227 | 152,176 | * |
| Rodman & Renshaw ⁽⁴¹⁾⁽⁴⁶⁾ | 356,020 | 272,959 | 83,061 | * |
| Shoreline Pacific, LLC ⁽⁴²⁾⁽⁴⁶⁾ | 54,750 | 54,750 | 0 | 0 |
| Dian Griesel, Ph.D. ⁽⁴³⁾ | 82,000 | 12,000 | 70,000 | * |
| Jeffrey Kraws ⁽⁴⁴⁾ | 62,000 | 4,000 | 58,000 | * |
| Total | 13,548,406 | 11,743,710 | 1,904,596 | 5.5% |

* Indicates less than 1%.

For each selling stockholder or warrant holder, the table above assumes the sale by that selling stockholder or warrant holder of all of its shares of common stock available for resale under this prospectus. For purposes of calculating the percentage of common stock owned upon completion of the offering, the table above (i) assumes 32,889,510 shares of common stock will be issued and outstanding upon completion of the offering, and (ii) includes the shares of common stock subject to warrants currently held by the selling stockholder or warrant holder (but not available for resale under this prospectus) as outstanding for computing the shares and percentage ownership of the person holding such warrants, but not outstanding for computing the percentage ownership of any other person or entity.

(1) Includes 138,607 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.

(2) Includes 84,819 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.

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- (3) Includes 131,119 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (4) Includes 65,000 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Alexandra Investment Management, LLC, a Delaware limited liability company (Alexandra), serves as investment advisor to Alexandra Global Master Fund Ltd., a British Virgin Islands company (Master Fund). By reason of such relationship, Alexandra may be deemed to share dispositive power over the shares of common stock stated as beneficially owned by Master Fund. Alexandra disclaims beneficial ownership of such shares of common stock. Messrs. Mikhail A. Filimonov (Filimonov) and Dimitri Sogoloff (Sogoloff) are managing members of Alexandra. By reason of such relationships, Filimonov and Sogoloff may be deemed to share dispositive power over the shares of common stock stated as beneficially owned by Master Fund. Filimonov and Sogoloff disclaim beneficial ownership of such shares of common stock.
- (5) Includes 32,500 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Basso Asset Management, L.P. (Basso) is the Investment Manager to Basso Multi-Strategy Holding Fund Ltd. Howard I. Fischer is a managing member of Basso GP, LLC, the General Partner of Basso.
- (6) Includes 99,167 shares subject to warrants held prior to the offering that are currently exercisable, of which 32,500 shares subject to warrants are being offered pursuant to this prospectus. Basso Equity Opportunity Holding Fund Ltd. was formerly known as AIG DKR SoundShore Private Investors Holding Fund Ltd. Basso Capital Management, L.P. (Basso) is the Investment Manager to Basso Equity Opportunity Holding Fund Ltd. Howard I. Fischer is a managing member of Basso GP, LLC, the General Partner of Basso.
- (7) Includes 23,637 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (8) Includes 35,455 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (9) Includes 18,200 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (10) Includes 82,728 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (11) Includes 189,091 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. As investment manager under a management agreement, Castle Creek LifeScience Partners, LLC may exercise dispositive and voting power with respect to the shares owned by CC LifeScience, Ltd. Castle Creek LifeScience Partners, LLC disclaims beneficial ownership of such shares. Daniel Asher and Nathan Fischel are the managing members of Castle Creek LifeScience Partners, LLC. Messrs. Asher and Fischel disclaim beneficial ownership of the shares owned by CC LifeScience, Ltd.
- (12) Includes 251,516 shares subject to warrants held prior to the offering that are currently exercisable, of which 118,182 shares subject to warrants are being offered pursuant to this prospectus. As investment manager under a management agreement, Castle Creek Partners, LLC may exercise dispositive and voting power with respect to the shares owned by Castle Creek Healthcare Partners LLC. Castle Creek Partners, LLC disclaims beneficial ownership of such shares. Daniel Asher is the managing member of Castle Creek Partners, LLC. Mr. Asher disclaims beneficial ownership of the shares owned by Castle Creek Healthcare Partners LLC.

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- (13) Includes 436,363 shares subject to warrants held prior to the offering that are currently exercisable, of which 236,363 shares subject to warrants are being offered pursuant to this prospectus.
- (14) Includes 78,000 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Mel Crow and Maxi Brezzi, in their capacity as managers of Green Light (Switzerland) SA, the investment advisor to Crescent International Ltd., have voting control and investment discretion over the shares owned by Crescent International Ltd. Messrs. Crow and Brezzi disclaim beneficial ownership of such shares.
- (15) Includes 21,645 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. DKR Saturn Management L.P. (DKR Saturn) is a registered investment adviser with the Securities and Exchange Commission and as such, is the investment manager to DKR Saturn Holdings Fund Ltd. (the Fund). DKR Saturn has retained certain individuals to act as the portfolio manager to the Fund managed by DKR Saturn. As such, DKR Saturn and certain portfolio managers have shared dispositive and voting power over the securities.
- (16) Includes 108,355 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. DKR Saturn Management L.P. (DKR Saturn) is a registered investment adviser with the Securities and Exchange Commission and as such, is the investment manager to DKR Saturn Event Driven Holding Fund Ltd. (the Fund). DKR Saturn has retained certain individuals to act as the portfolio manager to the Fund managed by DKR Saturn. As such, DKR Saturn and certain portfolio managers have shared dispositive and voting power over the securities.
- (17) Includes 26,000 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. The general partners of Elliott Associates, L.P. are Paul E. Singer and two entities controlled by him.
- (18) Includes 39,000 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. The general partner and investment manager of Elliott International, L.P. are controlled by Paul E. Singer.
- (19) Includes 236,364 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Heights Capital Management, Inc., the authorized agent of Capital Ventures International (CVI), has discretionary authority to vote and dispose of the shares held by CVI and may be deemed to be the beneficial owner of these shares. Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Mr. Kobinger disclaims any such beneficial ownership of the shares.
- (20) Includes 301,818 shares subject to warrants held prior to the offering that are currently exercisable, of which 141,818 shares subject to warrants are being offered pursuant to this prospectus.
- (21) Includes 296,667 shares subject to warrants held prior to the offering that are currently exercisable, of which 130,000 shares subject to warrants are being offered pursuant to this prospectus.
- (22) Includes 390,000 shares subject to warrants held prior to the offering that are currently exercisable, and are being offered pursuant to this prospectus.
- (23) Includes 251,515 shares subject to warrants held prior to the offering that are currently exercisable, of which 118,182 shares subject to warrants are being offered pursuant to this prospectus. The Investment Advisor to Portside Growth & Opportunity Fund is Ramius Capital

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Group, LLC. C4S & Co., LLC is the managing member of Ramius Capital Group, LLC. The managing members of C4S & Co., LLC are Peter A. Cohen, Morgan B. Stark and Thomas W. Strauss. Messrs. Cohen, Stark and Strauss could be deemed to be beneficial owners of the shares. As such, Messrs. Cohen, Stark and Strauss disclaim any beneficial ownership of the shares.

- (24) Includes 84,500 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (25) Includes 59,091 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. RHP Master Fund, Ltd. is a party to an investment management agreement with Rock Hill Investment Management, L.P., a limited partnership of which the general partner is RHP General Partner, LLC. Pursuant to such agreement, Rock Hill Investment Management directs the voting and disposition of shares owned by RHP Master Fund, Ltd. Messrs. Wayne Bloch, Gary Kaminsky and Peter Lockhart own all of the interests in RHP General Partner. The aforementioned entities and individuals disclaim beneficial ownership of the shares owned by RHP Master Fund, Ltd.
- (26) Includes 20,563 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. R & R Opportunity Fund LP is affiliated with Rodman & Renshaw, who served as a placement agent in the Company's August 2003 financing and the January 2004 financing.
- (27) Includes 23,636 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (28) Includes 118,182 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (29) Includes 47,273 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (30) Includes 11,818 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (31) Includes 130,000 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Michael A. Roth and Brian J. Stark are the founding members and direct the management of Staro Asset Management, L.L.C., a Wisconsin limited liability company ("Staro"), which acts as investment manager and has sole power to direct the management of SF Capital Partners Ltd. Through Staro, Messrs. Roth and Stark possess sole voting and dispositive power over all of the shares owned by SF Capital Partners Ltd.
- (32) Includes 284,849 shares subject to warrants held prior to the offering that are currently exercisable, of which 118,182 shares subject to warrants are being offered pursuant to this prospectus. Highbridge Capital Management, LLC is the trading manager of Smithfield Fiduciary LLC and has voting control and investment discretion over securities held by Smithfield Fiduciary LLC. Glen Dubin and Henry Swieca control Highbridge Capital Management, LLC. Each of Highbridge Capital Management, LLC, Glenn Dubin and Henry Swieca disclaims beneficial ownership of the securities held by Smithfield Fiduciary LLC.
- (33) Includes 35,100 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.

(34)

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Includes 318,182 shares subject to warrants held prior to the offering that are currently exercisable, of which 118,182 shares subject to warrants are being offered pursuant to this prospectus.

- ⁽³⁵⁾ Includes 57,525 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.

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- (36) Includes 39,975 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (37) Includes 328,900 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (38) Includes 321,100 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (39) Includes 115,820 shares subject to warrants held prior to the offering that are currently exercisable, of which 49,153 shares subject to warrants are being offered pursuant to this prospectus.
- (40) Includes 214,180 shares subject to warrants held prior to the offering that are currently exercisable, of which 80,847 shares subject to warrants are being offered pursuant to this prospectus.
- (41) Includes 356,020 shares subject to warrants held prior to the offering that are currently exercisable, of which 272,959 shares subject to warrants are being offered pursuant to this prospectus. Rodman & Renshaw served as a placement agent in the Company's August 2003 financing and the January 2004 financing.
- (42) Includes 54,750 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Shoreline Pacific, LLC served as a placement agent in the Company's August 2003 financing and the January 2004 financing.
- (43) Includes 82,000 shares subject to warrants held prior to the offering that are currently exercisable, of which 12,000 shares subject to warrants are being offered pursuant to this prospectus.
- (44) Includes 62,000 shares subject to warrants held prior to the offering that are currently exercisable, of which 4,000 shares subject to warrants are being offered pursuant to this prospectus.
- (45) The selling stockholder is an affiliate of a broker dealer and purchased the securities in the ordinary course of business. At the time this selling stockholder purchased the securities, it had no agreements or understandings, directly or indirectly, with any person to distribute the securities.
- (46) The selling stockholder is a broker dealer and is, therefore, deemed an underwriter by the Securities and Exchange Commission.

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PLAN OF DISTRIBUTION

We will not receive any part of the proceeds from the sale of common stock offered pursuant to this prospectus. The selling stockholders listed in the preceding section and any of their pledgees, assignees, donees 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 traded or in private transactions. These selling stockholders will act independently of us in making decisions with respect to the timing, manner and size of each sale. 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;

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 entered into after the date of this prospectus;

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 of 1933, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts 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 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 Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

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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 of 1933 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 of 1933. Each of the selling stockholders have informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock. Because the selling stockholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act of 1933.

Under current applicable rules and regulations of the Securities Exchange Act of 1934, any person engaged in the distribution of the shares may not simultaneously engage in market making activities with respect to our common stock for a period of at least two business days prior to the commencement of such distribution. In addition, each selling stockholder will be subject to applicable provisions of the Securities Exchange Act of 1934 and the associated rules and regulations under the Securities Exchange Act of 1934, including Regulation M, which provisions may limit the timing of purchases and sales of shares of our common stock by the selling stockholders. We will make copies of this prospectus available to the selling stockholders and have informed them of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of the shares being offered pursuant to this prospectus.

We are required to pay all fees and expenses incident to the registration of the shares. The Company and the Selling Stockholders have agreed to indemnify each other against certain losses, claims, damages and liabilities, including liabilities under the Securities Act of 1933.

LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed on by Stradling Yocca Carlson & Rauth, a Professional Corporation, Newport Beach, California.

EXPERTS

Ernst & Young LLP, independent auditors, have audited our financial statements included in our Annual Report on Form 10-K/A, Amendment No. 2 for the year ended June 30, 2003 as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

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WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed a registration statement on Form S-3 with the Securities and Exchange Commission relating to the common stock offered by this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. Statements contained in this prospectus as to the contents of any contract or other document referred to are not necessarily complete and in each instance reference is made to the copy of such contract or other document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference. For further information with respect to us and the common stock offered hereby, reference is made to such registration statement, exhibits and schedules.

We are subject to the information and periodic reporting requirements of the Securities Exchange Act of 1934, as amended, and in accordance therewith file reports, proxy statements and other information with the Securities and Exchange Commission. Such reports, proxy statements, other information and a copy of the registration statement may be inspected by anyone without charge and copies of these materials may be obtained upon the payment of the fees prescribed by the Securities and Exchange Commission, at the Public Reference Room maintained by the Securities and Exchange Commission at 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The registration statement and the reports, proxy statements and other information filed by us are also available through the Securities and Exchange Commission's Web site on the World Wide Web at the following address: <http://www.sec.gov>.

INCORPORATION BY REFERENCE

The Securities and Exchange Commission allows us to incorporate by reference the information we file with the Securities and Exchange Commission, which means that we can disclose important information to you by referring to those documents. We incorporate by reference the documents listed below and any additional documents filed by us with the Securities and Exchange Commission under Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until this offering of securities is terminated (File No. 001-16467). The information we incorporate by reference is an important part of this prospectus, and any information that we file later with the Securities and Exchange Commission will automatically update and supersede this information.

We hereby incorporate by reference the following documents:

1. Our Annual Report on Form 10-K for the fiscal year ended June 30, 2003 filed with the SEC on September 19, 2003, as amended by Form 10-K/A filed with the SEC on October 27, 2003, as further amended by Form 10-K/A filed with the SEC on March 2, 2004;
2. Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2003 filed with the SEC on November 10, 2003, as amended by Form 10-Q/A filed with the SEC on February 12, 2004;

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3. Our Quarterly Report on Form 10-Q for the quarter ended December 31, 2003 filed with the SEC on February 12, 2004;
4. Our Current Report on Form 8-K as filed with the SEC on August 22, 2003;
5. Our Current Report on Form 8-K as filed with the SEC on January 13, 2004;
6. Our Current Report on Form 8-K as filed with the SEC on February 23, 2004; and
7. The description of our common stock contained in our Registration Statement on Form 8-A, filed with the SEC under Section 12 of the Securities Exchange Act of 1934, including any amendment or report filed for the purpose of updating such description.

You may request a copy of these filings, at no cost, by writing or calling us at Cortex Pharmaceuticals, Inc., 15241 Barranca Parkway, Irvine, California 92618, telephone number (949) 727-3157, Attention: Chief Financial Officer.

Table of Contents**PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered hereunder. All of the amounts shown are estimates except for the SEC registration fee.

| | To be paid by Cortex Pharmaceuticals |
|------------------------|---|
| SEC registration fee | \$ 2,984 |
| Legal fees | \$ 60,000 |
| Accounting fees | \$ 25,000 |
| AMEX listing fees | \$ 22,500 |
| Miscellaneous expenses | \$ 5,000 |
| Total | \$ 115,484 |

Item 15. Indemnification of Directors and Officers

(a) As permitted by the Delaware General Corporation Law, our Restated Certificate of Incorporation, as amended, eliminates the liability of directors to the Company or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent otherwise prohibited by the Delaware General Corporation Law.

(b) Our Certificate of Incorporation provides that we will indemnify each person who was or is made a party to any proceeding by reason of the fact that such person is or was a director or officer of the Company against all expense, liability and loss reasonably incurred or suffered by such person in connection therewith to the fullest extent authorized by the Delaware General Corporation Law.

(c) Our Certificate of Incorporation also gives us the ability to enter into indemnification agreements with each of our officers and directors. We have entered into indemnification agreements with each of our directors and executive officers. The indemnification agreements provide for the indemnification of directors and officers against any and all expenses, judgements, fines, penalties and amounts paid in settlement, to the fullest extent permitted by law.

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Item 16. Exhibits

| Exhibit Number | Description |
|---------------------------|---|
| 5.1 | Opinion of Stradling Yocca Carlson & Rauth.* |
| 23.1 | Consent of Ernst & Young LLP, Independent Auditors. |
| 23.2 | Consent of Stradling Yocca Carlson & Rauth (see Exhibit 5.1). |

* *Previously filed.*

Item 17. Undertakings

(a) The undersigned registrant hereby undertakes:

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

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

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

(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) of this section do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and 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 the initial bona fide offering thereof.

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

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

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of 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 Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by us 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, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by us is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

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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 this Amendment No. 1 to 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 Irvine, State of California, on the 27 day of February 2004.

CORTEX PHARMACEUTICALS, INC.

By: /s/ MARIA S. MESSINGER

Chief Financial Officer

(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--|-------------------|
| /s/ ROGER G. STOLL, PH.D. _____ Roger G. Stoll, Ph.D. | President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer) | February 27, 2004 |
| /s/ MARIA S. MESSINGER _____ Maria S. Messinger | Chief Financial Officer (Principal Financial and Accounting Officer) | February 27, 2004 |
| * _____ Charles J. Casamento | Director | February 27, 2004 |
| * _____ Carl W. Cotman, Ph.D. | Director | February 27, 2004 |
| * _____ Peter F. Drake, Ph.D. | Director | February 27, 2004 |

*

Director

February 27, 2004

M. Ross Johnson, Ph.D.

* By: /s/ ROGER G. STOLL, Ph.D.

Roger G. Stoll, Ph.D.

Attorney-in-Fact

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EXHIBIT INDEX

Exhibit

| <u>Number</u> | <u>Description</u> |
|----------------------|---|
| 5.1 | Opinion of Stradling Yocca Carlson & Rauth.* |
| 23.1 | Consent of Ernst & Young LLP, Independent Auditors. |
| 23.2 | Consent of Stradling Yocca Carlson & Rauth (see Exhibit 5.1). |

* *Previously filed.*