

CORTEX PHARMACEUTICALS INC/DE/

Form S-3

January 13, 2005

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As Filed with the Securities and Exchange Commission on January 13, 2005

Registration No. _____

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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. 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 same 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 share(2) | Proposed maximum aggregate offering price | Amount of registration fee |
|---|---|---|--|---|
| Common Stock (\$0.001 par value) | 6,562,288 | \$2.64 | \$17,324,440 | \$2,040 |

(1) Includes (A) 4,233,333 shares of common stock issued to security holders pursuant to the terms of a Securities Purchase Agreement dated as of December 14, 2004 (Purchase Agreement), (B) 2,116,666 shares of common stock issuable upon exercise of warrants granted under the Purchase Agreement, (C) 164,289 shares of its common stock issuable upon exercise of warrants issued to a placement agent in connection with the Purchase Agreement, and (D) 48,000 shares of common stock issuable upon exercise of warrants previously issued. Pursuant to Rule 416 under the Securities Act, this Registration Statement also covers such additional number of shares of common stock as may be issuable upon a stock split, stock dividend or similar transaction.

(2) The offering price is estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c), using the average of the high and low prices of the Registrant's Common Stock as reported on The American Stock Exchange on January 7, 2005, which was approximately \$2.64 per share.

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 JANUARY 13, 2005

PROSPECTUS

CORTEX PHARMACEUTICALS, INC.

6,562,288 Shares of Common Stock

(\$0.001 par value)

This prospectus relates to the offer and sale from time to time of up to 4,233,333 shares of our outstanding common stock, and up to 2,328,955 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 January 12, 2005, the last reported sale price of our common stock was \$2.79 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 _____, 2005.

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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, require less time to develop 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 and other neurodegenerative diseases and disorders.

Internally we are investigating the applicability of AMPAKINE compounds to treatment of fragile X syndrome, autism, loss of memory due to ECT (electroconvulsive therapy for depression), narcolepsy and the effects of sleep deprivation.

We continue to have discussions regarding potential collaborative or licensing arrangements with other large pharmaceutical companies for large market opportunities and to develop opportunities for our direct commercialization of Orphan Drug opportunities. Since October 2002, we have secured approximately \$45,000,000 in funding to help support our research and development efforts.

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

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incurred net losses through September 30, 2004 approximating \$49,563,000. 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 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 September 30, 2004, we have generated only modest operating revenues and we have incurred net losses approximating \$49,563,000. For the fiscal years ended June 30, 2002, 2003 and 2004, and the three-month period ended September 30, 2004, our net losses amounted to \$983,000, \$1,175,000, \$5,994,000 and \$1,511,000, respectively. As of September 30, 2004, we had an accumulated deficit of approximately \$51,594,000. 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. Additional funds also may result from the exercise of warrants to purchase shares of our common stock. As of December 31, 2004, warrants to purchase up to approximately 10.4 million shares of our common stock were outstanding. If these warrants are fully exercised, of which there can be no assurance, such exercise would provide approximately \$31,000,000 of additional capital.

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;

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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.

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 \$70,000. 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. Clinical trials for the AMPAKINE compound CX717 were initiated in May 2004, which assure us of meeting the requirement to initiate testing of a compound other than CX516 during the required timeframe. 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 that we maintain a strong relationship with the University.

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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. 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. Such trials are being funded by third parties and do not involve financial commitments from us.

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.

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, 2004 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, 2004, we have received an up-front payment of \$5,000,000 and research support payments of approximately \$12,495,000. Under the October 2000 agreement, as amended to date, we currently receive approximately \$2,165,000 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. 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 December 31, 2005. 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. Both we and Servier have the right to terminate the agreement on an annual basis upon six-months' prior notice. In addition, either party has the right to terminate the related research and development in the event that the other party materially breaches 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 rights for the promotion of selected AMPAKINE compounds for Orphan Drug indications. Such rights may or may not be obtainable from potential future partners. 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. We maintain a positive relationship with Dr. Lynch and continue to fund research in his laboratory related to understanding the molecular actions of the AMPAKINE compounds and the AMPA receptor.

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 \$10 million per occurrence and \$10 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 risks related to the trials, but we cannot assure you that the coverage limits of our insurance policies

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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 Pharmaceutical Research and Manufacturers of America, historically the cost of developing a new

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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 the six-month period ended December 31, 2004 and fiscal years ended June 30, 2004 and June 30, 2003, as quoted on The American Stock Exchange, was \$1.40 to \$3.10, \$1.62 to \$4.99, \$0.51 to \$2.49, 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;

public concern over the safety of therapeutic products; and

changes in healthcare reimbursement policies and healthcare regulations.

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 4,233,333 shares will become freely tradable without restriction. If all outstanding warrants and options are exercised prior to their expiration, approximately 16.9 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 4,233,333 shares of common stock and five-year warrants to purchase an additional 2,116,666 shares of common stock at an exercise price of \$3.00 per share on December 14, 2004 in a private placement to certain stockholders who are accredited investors. Pursuant to a Registration Rights Agreement dated December 14, 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 February 1, 2004 and January 13, 2005 we issued warrants to purchase 212,289 shares of common stock, including warrants to purchase 164,289 shares of common stock to a placement agent 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 |
|--|---|---|--|---|
| Basso Multi-Strategy Holding Fund Ltd. ⁽¹⁾ | 312,500 | 237,000 | 75,500 | * |
| Basso Private Opportunity Holding Fund Ltd. ⁽²⁾ | 227,434 | 63,000 | 164,434 | * |
| Bristol Investment Fund, Ltd. ⁽³⁾ | 422,932 | 422,932 | 0 | 0 |
| CC LifeScience, Ltd. ^{(4) (28)} | 761,955 | 281,955 | 480,000 | 1.4 |
| Cohanzick Absolute Return Master Fund, Ltd. ⁽⁵⁾ | 37,500 | 37,500 | 0 | 0 |
| Cranshire Capital, L.P. ⁽⁶⁾ | 828,690 | 300,000 | 528,690 | 1.5 |

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| | | | | |
|---|------------|-----------|-----------|-------|
| Crescent International Ltd. ⁽⁷⁾ | 278,000 | 150,000 | 128,000 | * |
| Gabriel Capital, L.P. ⁽⁸⁾ | 112,500 | 112,500 | 0 | 0 |
| Platinum Partners LP ⁽⁹⁾ | 150,000 | 150,000 | 0 | 0 |
| Portside Growth and Opportunity Fund ^{(10) (28)} | 555,388 | 281,955 | 273,433 | * |
| Quogue Capital LLC ⁽¹¹⁾ | 234,500 | 150,000 | 84,500 | * |
| Ronald L. Chez, IRA ⁽¹²⁾ | 812,028 | 451,128 | 360,900 | 1.0 |
| Silverback Life Sciences Master Fund Ltd. ⁽¹³⁾ | 676,671 | 676,671 | 0 | 0 |
| SF Capital Partners Ltd. ^{(14) (28)} | 1,485,000 | 1,155,000 | 330,000 | * |
| Solomon Strategic Holdings, Inc. ⁽¹⁵⁾ | 41,166 | 41,166 | 0 | 0 |
| Spectra Capital Management, LLC ^{(16) (28)} | 151,253 | 84,586 | 66,667 | * |
| SRG Capital LLC ^{(17) (28)} | 185,455 | 150,000 | 35,455 | * |
| TCMP3 Partners ⁽¹⁸⁾ | 204,273 | 169,173 | 35,100 | * |
| The Tail Wind Fund Limited ⁽¹⁹⁾ | 864,833 | 422,933 | 441,900 | 1.3 |
| Vicis Capital Master Fund ⁽²⁰⁾ | 112,500 | 112,500 | 0 | 0 |
| Xmark Fund, L.P. ⁽²¹⁾ | 644,388 | 225,000 | 419,388 | 1.2 |
| Xmark Fund, Ltd. ⁽²²⁾ | 817,438 | 225,000 | 592,438 | 1.7 |
| Xmark Opportunity Fund, L.P. ⁽²³⁾ | 225,000 | 225,000 | 0 | 0 |
| Xmark Opportunity Fund, Ltd. ⁽²⁴⁾ | 225,000 | 225,000 | 0 | 0 |
| Rodman & Renshaw LLC ^{(25) (29)} | 520,309 | 164,289 | 356,020 | 1.0 |
| Dian Griesel, Ph.D. ⁽²⁶⁾ | 125,000 | 43,000 | 82,000 | * |
| Jeffrey Kraws ⁽²⁷⁾ | 67,000 | 5,000 | 62,000 | * |
| Total | 11,078,713 | 6,562,288 | 4,516,425 | 12.0% |

* 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 35,017,591 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 111,500 shares subject to warrants held prior to the offering that are currently exercisable, of which 79,000 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, and as such has investment power and voting control over these securities. Mr. Fischer disclaims beneficial ownership of these securities.

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- (2) Includes 120,167 shares subject to warrants held prior to the offering that are currently exercisable, of which 21,000 are being offered pursuant to this prospectus. Basso Capital Management, L.P. (Basso) is the Investment Manager to Basso Private Opportunity Holding Fund Ltd. Howard I. Fischer is a managing member of Basso GP, LLC, the General Partner of Basso, and as such has investment power and voting control over these securities. Mr. Fischer disclaims beneficial ownership of these securities.
- (3) Includes 140,977 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Paul Kessler, as manager of Bristol Capital Advisors, LLC, the investment manager to Bristol Investment Fund, Ltd., has voting and investment control over the securities held by Bristol Investment Fund, Ltd. Mr. Kessler disclaims beneficial ownership of the securities held by Bristol Investment Fund, Ltd.
- (4) Includes 283,076 shares subject to warrants held prior to the offering that are currently exercisable, of which 93,985 shares subject to warrants 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. Nathan Fischel is the managing member of Castle Creek LifeScience Partners, LLC. Mr. Fischel disclaims beneficial ownership of the shares owned by CC LifeScience, Ltd.
- (5) Includes 12,500 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. David Sherman, as an authorized agent of Cohanzick Absolute Return Master Fund, Ltd., has voting and investment control over the securities held by such entity.
- (6) Includes 536,363 shares subject to warrants held prior to the offering that are currently exercisable, of which 100,000 are being offered pursuant to this prospectus. Mitchell P. Kopin, president of Downsview Capital, Inc. which is the general partner of Cranshire Capital, L.P., has sole voting and investment control over the securities held by Cranshire Capital, L.P.
- (7) Includes 128,000 shares subject to warrants held prior to the offering that are currently exercisable, of which 50,000 shares subject to warrants are being offered pursuant to this prospectus. Mel Crow and Maxi Brezzi, in their capacity as managers of GreenLight (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.
- (8) Includes 37,500 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. David Sherman, as an authorized agent of Gabriel Capital, L.P., has voting and investment control over the securities held by such entity.
- (9) Includes 50,000 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Mark Nordlicht, as a managing member of Platinum Partners LP, has voting and investment control over the securities held by such entity.
- (10) Includes 345,500 shares subject to warrants held prior to the offering that are currently exercisable, of which 93,985 shares subject to warrants are being offered pursuant to this

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prospectus. Ramius Capital Group, LLC (Ramius Capital) is the investment adviser of Portside Growth & Opportunity Fund (Portside) and consequently has voting control and investment discretion over securities held by Portside. Ramius Capital disclaims beneficial ownership of the shares held by Portside. Peter A. Cohen, Morgan B. Stark, Thomas W. Strauss and Jeffrey M. Solomon are the sole managing members of C4S & Co., LLC, the sole managing member of Ramius Capital. As a result, Messrs. Cohen, Stark, Strauss and Solomon may be considered beneficial owners of any shares deemed to be beneficially owned by Ramius Capital. Messrs. Cohen, Stark, Strauss and Solomon disclaim beneficial ownership of these shares.

- (11) Includes 134,500 shares subject to warrants held prior to the offering that are currently exercisable, of which 50,000 shares subject to warrants are being offered pursuant to this prospectus. Wayne Rothbaum is a principal of Quogue Capital LLC and has voting and investment control over the securities held by such entity.
- (12) Includes 150,376 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (13) Includes 225,557 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus. Elliot Bossen has voting and dispositive control over the securities held by Silverback Life Sciences Master Fund Ltd.
- (14) Includes 515,000 shares subject to warrants held prior to the offering that are currently exercisable, of which 385,000 shares subject to warrants are being offered pursuant to this prospectus. Michael A. Roth and Brian J. Stark possess sole voting and dispositive power over all of the shares owned by SF Capital Partners Ltd.
- (15) Includes 13,722 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (16) Includes 94,862 shares subject to warrants held prior to the offering that are currently exercisable, of which 28,195 shares subject to warrants are being offered pursuant to this prospectus. Gregory I. Dorges is a member of Spectra Capital Management, LLC and has voting and investment control over the securities held by such entity.
- (17) Includes 85,455 shares subject to warrants held prior to the offering that are currently exercisable, of which 50,000 shares subject to warrants are being offered pursuant to this prospectus. Edwin Mecabe and Tai May Lee jointly have voting and investment control over the securities held by SRG Capital LLC.
- (18) Includes 91,491 shares subject to warrants held prior to the offering that are currently exercisable, of which 56,391 shares subject to warrants are being offered pursuant to this prospectus. Steven E. Slawson is a principal of TCMP3 Partners and has voting and investment control over the securities held by such entity.
- (19) Includes 459,160 shares subject to warrants held prior to the offering that are currently exercisable, of which 140,978 shares subject to warrants are being offered pursuant to this prospectus. Tail Wind Advisory & Management Ltd., a UK corporation authorized and regulated by the Financial Services Authority of Great Britain (TWAM), is the investment manager for The Tail Wind Fund Ltd., and David Crook is the CEO and controlling shareholder of TWAM. Each of TWAM and David Crook expressly disclaims any equitable or beneficial ownership of, or pecuniary interest in, the shares being registered hereunder and held by The Tail Wind Fund Ltd.

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- (20) Includes 37,500 shares subject to warrants held prior to the offering that are currently exercisable and are being offered pursuant to this prospectus.
- (21) Consists of (i) 453,568 shares held by Xmark Fund, L.P., of which 150,000 shares are being offered pursuant to this prospectus; and (ii) 190,820 shares issuable upon exercise of warrants held by Xmark Fund, L.P., of which 75,000 shares are being offered pursuant to this prospectus. Xmark Asset Management, LLC (XAM) serves as investment manager for Xmark Fund, L.P., as well as for various other private investment funds. Mitchell D. Kaye, whose business address is c/o Xmark Asset Management, LLC, 152 West 57th Street, 21st Floor, New York, New York 10019, is the Manager of XAM, and as such, Mr. Kaye possesses the power to vote and direct the disposition of the securities held by Xmark Fund, L.P.
- (22) Consists of (i) 528,258 shares held by Xmark Fund, Ltd., of which 150,000 shares are being offered pursuant to this prospectus; and (ii) 289,180 shares issuable upon the exercise of warrants held by Xmark Fund, Ltd., of which 75,000 shares are being offered pursuant to this prospectus. XAM serves as investment manager for Xmark Fund, Ltd., as well as for various other private investment funds. Mitchell D. Kaye, whose business address is c/o Xmark Asset Management, LLC, 152 West 57th Street, 21st Floor, New York, New York 10019, is the Manager of XAM, and as such, Mr. Kaye possesses the power to vote and direct the disposition of the securities held by Xmark Fund, Ltd.
- (23) Consists of (i) 150,000 shares held by Xmark Opportunity Fund, L.P., all of which are being offered pursuant to this prospectus; and (ii) 75,000 shares issuable upon the exercise of warrants held by Xmark Opportunity Fund, L.P., all of which are being offered pursuant to this prospectus. Xmark Opportunity GP, LLC serves as the general partner of Xmark Opportunity Fund, L.P. Xmark Opportunity Partners, LLC is the sole member of Xmark Opportunity GP, LLC. Xmark Capital Partners, LLC serves as the managing member of Xmark Opportunity Partners, LLC. Mitchell D. Kaye and David C. Cavalier, whose business address is c/o Xmark Capital Partners, LLC, 152 West 57th Street, 21st Floor, New York, New York 10019, are the sole members of the management committee of Xmark Capital Partners, LLC, and as such, Mr. Kaye and Mr. Cavalier possess the power to vote and direct the disposition of the securities held by Xmark Opportunity Fund, L.P.
- (24) Consists of (i) 150,000 shares held by Xmark Opportunity Fund, Ltd., all of which are being offered pursuant to this prospectus; and (ii) 75,000 shares issuable upon the exercise of warrants held by Xmark Opportunity Fund, Ltd., all of which are being offered pursuant to this prospectus. Xmark Opportunity MC, LLC serves as investment manager for Xmark Opportunity Fund, Ltd. Xmark Opportunity Partners, LLC is the sole member of Xmark Opportunity MC, LLC. Xmark Capital Partners, LLC serves as the managing member of Xmark Opportunity Partners, LLC. Mitchell D. Kaye and David C. Cavalier, whose business address is c/o Xmark Capital Partners, LLC, 152 West 57th Street, 21st Floor, New York, New York 10019, are the sole members of the management committee of Xmark Capital Partners, LLC, and as such, Mr. Kaye and Mr. Cavalier possess the power to vote and direct the disposition of the securities held by Xmark Opportunity Fund, Ltd.
- (25) Consists of 520,309 shares subject to warrants held prior to the offering that are currently exercisable, of which 164,289 shares subject to warrants are being offered pursuant to this prospectus. Rodman & Renshaw LLC served as a placement agent in the Company's August 2003, January 2004 and December 2004 financings. Thomas G. Pinou is the Chief Financial Officer of Rodman & Renshaw LLC and has voting and investment control over the securities held by such entity.
- (26) Consists of 70,000 shares subject to warrants held prior to the offering that are currently exercisable, of which 43,000 shares subject to warrants are being offered pursuant to this prospectus.

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- (27) Consists of 67,000 shares subject to warrants held prior to the offering that are currently exercisable, of which 5,000 shares subject to warrants are being offered pursuant to this prospectus.
- (28) 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.
- (29) 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;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

a combination of any such methods of sale; or

any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended (the Securities Act), 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.

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In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume.

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The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

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. Each selling stockholder has informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

We are required to pay certain fees and expenses incurred by the Company incident to the registration of the shares. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

Because the selling stockholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. Each selling stockholder has advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling stockholders.

We agreed to keep the registration statement of which this prospectus is part effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without volume restrictions pursuant to Rule 144(k) or (ii) all of the shares have been sold pursuant to the registration statement of which this prospectus is part or Rule 144 under the Securities Act or any other rule of similar effect. The resale shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended (the Exchange Act), any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

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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 registered public accounting firm, have audited our financial statements included in our Annual Report on Form 10-K, for the year ended June 30, 2004 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, 2004 filed with the SEC on September 27, 2004, as amended by Form 10-K/A filed with the SEC on October 28, 2004;
2. Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 filed with the SEC on November 15, 2004;
3. Our Current Reports on Form 8-K as filed with the SEC on November 10, 2004 (as amended on December 1, 2004), December 7, 2004, December 20, 2004 and December 23, 2004;

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4. Our Proxy Statement dated November 12, 2004 relating to the Annual Meeting of Stockholders held on December 16, 2004; and
5. 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 and the AMEX listing fees.

| | To be paid by Cortex Pharmaceuticals |
|------------------------|---|
| SEC registration fee | \$ 2,040 |
| Legal fees | \$ 30,000 |
| Accounting fees | \$ 12,500 |
| AMEX listing fees | \$ 37,500 |
| Miscellaneous expenses | \$ 5,000 |
| Total | \$ 87,040 |

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, judgments, fines, penalties and amounts paid in settlement, to the fullest extent permitted by law.

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Item 16. Exhibits

| <u>Exhibit Number</u> | <u>Description</u> |
|---------------------------|--|
| 5.1 | Opinion of Stradling Yocca Carlson & Rauth. |
| 23.1 | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. |
| 23.2 | Consent of Stradling Yocca Carlson & Rauth (see Exhibit 5.1). |
| 24.1 | Power of Attorney (included on the signature page hereof). |

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.

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(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 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.

Table of Contents**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 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 13th day of January, 2005.

CORTEX PHARMACEUTICALS, INC.

By: /s/ Maria S. Messinger
 Maria S. Messinger
 Chief Financial Officer
 (Principal Financial and Accounting Officer)

POWER OF ATTORNEY

We, the undersigned directors and officers of Cortex Pharmaceuticals, Inc., do hereby constitute and appoint Roger G. Stoll, Ph.D. and Maria S. Messinger, or either of them, our true and lawful attorneys and agents, to do any and all acts and things in our name and behalf in our capacities as directors and officers and to execute any and all instruments for us and in our names in the capacities indicated below, which said attorneys and agents, or either of them, may deem necessary or advisable to enable said corporation to comply with the Securities Act of 1933, as amended, and any rules, regulations, and requirements of the Securities and Exchange Commission, in connection with this registration statement, including specifically, but without limitation, power and authority to sign for us or any of us in our names and in the capacities indicated below, any and all amendments (including post-effective amendments) to this registration statement, or any related registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act of 1933, as amended; and we do hereby ratify and confirm all that the said attorneys and agents, or either of them, shall 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 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) | January 13, 2005 |
| /s/ Maria S. Messinger _____ Maria S. Messinger | Chief Financial Officer (Principal Financial and Accounting Officer) | January 13, 2005 |
| /s/ Robert F. Allnutt | Director | January 13, 2005 |

Robert F. Allnutt

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| <u>Signature</u> | <u>Title</u> | <u>Date</u> |
|---|--------------|------------------|
| <u>/s/ Charles J. Casamento</u> Charles J. Casamento | Director | January 13, 2005 |
| <u>/s/ Carl W. Cotman, Ph.D.</u> Carl W. Cotman, Ph.D. | Director | January 13, 2005 |
| <u>/s/ Peter F. Drake, Ph.D.</u> Peter F. Drake, Ph.D. | Director | January 13, 2005 |
| <u>/s/ M. Ross Johnson, Ph.D.</u> M. Ross Johnson, Ph.D. | Director | January 13, 2005 |
| <u>/s/ Gary D. Tollefson, M.D., Ph.D.</u> Gary D. Tollefson, M.D., Ph.D. | Director | January 13, 2005 |

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EXHIBIT INDEX

| <u>Exhibit Number</u> | <u>Description</u> |
|----------------------------------|--|
| 5.1 | Opinion of Stradling Yocca Carlson & Rauth. |
| 23.1 | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm. |
| 23.2 | Consent of Stradling Yocca Carlson & Rauth (see Exhibit 5.1). |
| 24.1 | Power of Attorney (included on the signature page hereof). |