CORTEX PHARMACEUTICALS INC/DE/ Form S-3 September 19, 2003 Table of Contents

As Filed with the Securities and Exchange Commission on September 19, 2003

Registration No. 333-

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. $\ddot{}$

		Proposed	Proposed			
		maximum	maximum			
Title of each class of securities	Amount to be	offering price	aggregate offering	Amount of		
to be registered	registered(1)	per share (2)	price	registration fee		
Common Stock (\$.001 par value)	7,307,729	\$4.09	\$29,888,612	\$2,418		

CALCULATION OF REGISTRATION FEE

(1) Includes (A) 3,333,334 shares of common stock issued to security holders pursuant to the terms of a Securities Purchase Agreement dated as of August 21, 2003 (Purchase Agreement), (B) 3,333,334 shares of common stock issuable upon exercise of warrants granted under the Purchase Agreement, (C) 113,061 shares of its common stock issuable upon exercise of warrants issued to placement agents in connection with the Purchase Agreement, and (D) 528,000 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 September 17, 2003, which was approximately \$4.09 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.

SUBJECT TO COMPLETION, DATED SEPTEMBER 19, 2003

PROSPECTUS

CORTEX PHARMACEUTICALS, INC.

7,307,729 Shares of Common Stock

(\$0.001 par value)

This prospectus relates to the offer and sale from time to time of up to 3,333,334 shares of our outstanding common stock, and up to 3,974,395 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 September 18, 2003, the last reported sale price of our common stock was \$4.40 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.

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The date of this Prospectus is September _____, 2003.

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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 the ability to compete) and eventually to participate more fully in the commercial development of AMPAKINE products in the United States.

We currently have a research collaboration and 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.

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 ide 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 above and in the documents incorporated by reference. We undertake no duty to update any of these forward-looking statements.

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.

If we cannot raise capital on acceptable terms, we may need to significantly curtail our operations.

Without further infusions of capital, we anticipate that we have sufficient funds and committed sources of funding from Servier to maintain our operations into fiscal year 2005. We will require additional funds to continue our operations beyond that time. We cannot say with any amount of certainty that we will be able to obtain the additional needed funds on reasonable terms, or at all. We currently do not have sufficient authorized shares of common stock to undertake any significant common stock financing and we will need to obtain stockholder approval to authorize more shares of common stock. If we do not obtain such approval we will not be able to raise additional funds by the sale of common stock, or securities convertible into common stock. If we do obtain such approval and raise additional funds by issuing more of our securities, stockholders at the time of issuance will experience a dilution to the value of their securities.

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 time frame, or at all.

If we are unable to obtain additional funds, we could lose our key employees and could be required to abandon one or more of our product development programs. In addition, we may be unable to meet our research spending obligations under existing licensing agreements and may be unable to continue our business operations.

We are presently seeking collaborative or other arrangements with larger pharmaceutical companies to provide for both our immediate and longer-term funding requirements. 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.

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

We are dependent on future payments from Organon and Servier to continue the development and commercialization of our AMPAKINE technology. 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 June 30, 2003 we have received \$6,000,000 in up-front and milestone payments and approximately \$6,000,000 in research support payments. The agreement also includes milestone payments, plus royalty payments on a worldwide basis. We anticipate that we may trigger an additional milestone during the fiscal year ending June 30, 2004, although there is no assurance that such milestone will occur. Under the terms of the agreement, Organon has the right to terminate the agreement upon four-months prior notice. If Organon were to discontinue its financial support, we might not be able to continue the development of our AMPAKINE technology as a potential treatment for patients with schizophrenia and depression.

Under the agreement with Servier that we entered into in October 2000 and amended in October 2002, 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 June 30, 2003, we have received an up-front payment of \$5,000,000 and research support payments of approximately \$7,800,000. Under the October 2000 agreement, 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 into early December 2003. Under the October 2002 amendment, we currently receive an additional \$2,000,000 per year, which Servier is obligated to continue into early October 2004. The agreement includes milestone payments, plus royalty payments on sales in licensed territories. We do not anticipate that any milestone payments from Servier will occur 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 and development in the event that we materially breach the agreement. If Servier were to discontinue its financial support, we might not be able to continue the development of our AMPAKINE technology for the applications licensed to Servier and our financial condition could be seriously impaired.

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 June 30, 2003, we have generated only modest operating revenues and we have incurred net losses approximating \$42,057,000. As of June 30, 2003, we had an accumulated deficit of approximately \$44,089,000. 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 require substantial additional funds to advance our research and development programs, particularly if we decide to independently conduct later-stage clinical testing and apply for regulatory approval of any of our proposed products.

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. 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 U.S.

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. 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. 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 at least five years, either directly or through our corporate partners or licensees.

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 require us to make certain minimum annual payments, meet certain milestones or diligently seek to commercialize the underlying technology. Our failure to meet any of these requirements could allow the University to terminate that particular agreement.

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.

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 3,333,334 shares will become freely tradable without restriction. If all outstanding warrants and options are exercised prior to their expiration, approximately 7.3 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.

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. 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. 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.

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 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. Our agreements with Dr. Lynch and our other consultants are generally terminable by the consultant on short notice.

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. 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.

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 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 fall:

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

Our charter document and shareholder rights plan may discourage companies from acquiring us and offering our stockholders a premium for their shares, and could adversely affect the market price of our common stock.

Certain provisions of our certificate of incorporation 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 certificate of incorporation 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 shareholder rights plan may have the effect of delaying, deferring or preventing a change in control of our business. This may discourage bids for our common stock at a premium over the market price of the common stock and may adversely affect the market price of our common stock.

We may fail to continue to meet the listing standards for the American Stock Exchange and, in the event that our common stock is delisted from such exchange, the liquidity of our common stock is likely to be impaired and the market price of our shares could be adversely affected.

The listing standards for the American Stock Exchange include a stockholders equity and market capitalization test. The Exchange also monitors the financial condition and stability of listed companies. As of June 30, 2003, we had a stockholders deficit of approximately \$1,400,000, which does not meet the current listing standards. With the estimated net proceeds from the private placement of the Company s common stock in August 2003, the Company believes that it will meet the current listing standards.

In the event that we fail to satisfy the listing standards on a continuous basis, the Exchange will contact us regarding our status. Within 30 days of such contact, we can provide the Exchange with our plan of action to bring us into compliance with the listing standards within 18 months of the contact by the Exchange. If we do not provide a plan or if the Exchange does not accept our plan, delisting procedures will commence. If our plan is accepted, the Exchange will review our compliance with the plan on a quarterly basis. If we do not show progress consistent with our plan, delisting procedures may begin. If our common stock is removed from listing on the Exchange, the liquidity of our common stock is likely to be impaired and the trading price reduced.

Changes in laws, regulations and financial accounting standards may affect our reported results of operations.

The recently enacted Sarbanes-Oxley Act of 2002 and related regulations may result in changes in accounting standards or accepted practices within our industry and could add significant new costs to being a public company. New pronouncements and varying interpretations of pronouncements have occurred in the past and are likely to occur in the future as a result of recent Congressional and regulatory actions. New laws, regulations, and accounting standards, as well as potential changes to currently accepted accounting practices in the technology industry, including the expensing of stock options, could adversely affect our reported financial results and negatively impact our stock price. Additional unanticipated expenses incurred to comply with new requirements could also negatively impact our results of operations.

USE OF PROCEEDS

The proceeds from the sale of each selling stockholder s common stock will belong to that selling stockholder. We will not receive any proceeds from such sales.

SELLING STOCKHOLDERS

We issued 3,333,334 shares of common stock and warrants to purchase an additional 3,333,334 shares of common stock on August 21, 2003 in a private placement to certain stockholders set forth below. Pursuant to a Registration Rights Agreement dated August 21, 2003, 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 July 1999 and September 2003 we issued warrants to purchase 641,061 shares of common stock. Under each of these warrants we are required to include the shares underlying those warrant in the registration statement of which this prospectus is a part.

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

The following table sets forth: (1) the name of each of the selling stockholders 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 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 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
AIG DKR Soundshore Private Investors Holding Fund ⁽¹⁾	133,334	133,334	0	0
Castle Creek Healthcare Partners LLC ⁽²⁾	266,668	266,668	0	0
Cranshire Capital, L.P. ⁽³⁾	400,000	400,000	0	0
Gryphon Master Fund, LP ⁽⁴⁾	333,334	333,334	0	0
Langley Partners, L.P. ⁽⁵⁾	320,000	320,000	0	0
Alpha Capital AG ⁽⁶⁾	333,334	333,334	0	0
Omicron Master Trust ⁽⁷⁾	333,334	333,334	0	0
Orion Biomedical Fund, LP ⁽⁸⁾	821,500	821,500	0	0



Orion Biomedical Offshore Fund, LP ⁽⁹⁾	178,500	178,500	0	0
OTAPE Investments LLC ⁽¹⁰⁾	333,334	333,334	0	0
Platinum Partners Value Arbitrage Fund LP ⁽¹¹⁾	266,666	266,666	0	0
Portside Growth and Opportunity Fund ⁽¹²⁾	266,666	266,666	0	0
Promed Offshore Fund, Ltd. ⁽¹³⁾	97,470	97,470	0	0
Promed Partners, L.P. ⁽¹⁴⁾	569,200	569,200	0	0
Smithfield Fiduciary, LLC ⁽¹⁵⁾	333,334	333,334	0	0
Spectra Capital Management ⁽¹⁶⁾	133,334	133,334	0	0
The Tail Wind Fund Limited ⁽¹⁷⁾	400,000	400,000	0	0
Xmark Fund, L.P. ⁽¹⁸⁾	133,334	133,334	0	0
Xmark Fund, Ltd. ⁽¹⁹⁾	266,666	266,666	0	0
Patience Partners, L.P. ⁽²⁰⁾	66,666	66,666	0	0
Bristol Investment Fund, Ltd. ⁽²¹⁾	413,328	413,328	0	0
Robert D. Van Roijen ⁽²²⁾	266,666	266,666	0	0
Rodman & Renshaw ⁽²³⁾	83,061	83,061	0	0
Shoreline Pacific, LLC ⁽²⁴⁾	30,000	30,000	0	0
Alkermes, Inc. ⁽²⁵⁾	200,000	200,000	0	0
Robert C. Elliott ⁽²⁶⁾	54,000	54,000	0	0
Bernhard Hoffman ⁽²⁶⁾	54,000	54,000	0	0
Daniel P. Stauder ⁽²⁶⁾	54,000	54,000	0	0
Paul O. Landini ⁽²⁷⁾	38,000	38,000	0	0
Dian Griesel, Ph.D. ⁽²⁸⁾	70,000	70,000	0	0
Jeffrey Kraws ⁽²⁹⁾	58,000	58,000	0	0
Total	7,307,729	7,307,729	0	0%
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For each selling stockholder, the table above assumes the sale by that selling stockholder of all of its shares of common stock available for resale under this prospectus.

- (1) Includes 66,667 shares subject to warrants that are currently exercisable.
- (2) Includes 133,334 shares subject to warrants that are currently exercisable.
- (3) Includes 200,000 shares subject to warrants that are currently exercisable.
- (4) Includes 166,667 shares subject to warrants that are currently exercisable.
- (5) Includes 160,000 shares subject to warrants that are currently exercisable.
- (6) Includes 166,667 shares subject to warrants that are currently exercisable.
- (7) Includes 166,667 shares subject to warrants that are currently exercisable.
- (8) Includes 410,750 shares subject to warrants that are currently exercisable.
- (9) Includes 89,250 shares subject to warrants that are currently exercisable.
- (10) Includes 166,667 shares subject to warrants that are currently exercisable.
- (11) Includes 133,333 shares subject to warrants that are currently exercisable.
- (12) Includes 133,333 shares subject to warrants that are currently exercisable. The Investment Advisor to Portside Growth & Opportunity Fund is Ramius Capital 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.
- (13) Includes 48,735 shares subject to warrants that are currently exercisable.
- (14) Includes 284,600 shares subject to warrants that are currently exercisable.
- (15) Includes 166,667 shares subject to warrants that are currently exercisable.
- (16) Includes 66,667 shares subject to warrants that are currently exercisable.
- (17) Includes 200,000 shares subject to warrants that are currently exercisable.
- (18) Includes 66,667 shares subject to warrants that are currently exercisable.

- (19) Includes 133,333 shares subject to warrants that are currently exercisable.
- (20) Includes 33,333 shares subject to warrants that are currently exercisable.
- (21) Includes 206,664 shares subject to warrants that are currently exercisable.
- (22) Includes 133,333 shares subject to warrants that are currently exercisable.
- (23) Includes 83,061 shares subject to warrants that are currently exercisable.

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- (24) Includes 30,000 shares subject to warrants that are currently exercisable.
- (25) Includes 200,000 shares subject to warrants that are currently exercisable.
- (26) Includes 54,000 shares subject to warrants that are not currently exercisable and may become exercisable upon certain conditions.
- (27) Includes 38,000 shares subject to warrants that are not currently exercisable and may become exercisable upon certain conditions.
- (28) Includes 70,000 shares subject to warrants that are currently exercisable.
- (29) Includes 58,000 shares subject to warrants that are currently exercisable.

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;

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 stockh