CORTEX PHARMACEUTICALS INC/DE/
Form 10-K/A
March 02, 2004
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

AMENDMENT NO. 2

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2003

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 0-17951

Cortex Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**33-0303583**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

15241 Barranca Parkway, Irvine, California 92618

(Address of principal executive offices)

Registrant s telephone number, including area code: (949) 727-3157

Securities Registered Pursuant to Section 12(b) of the Act:

Common Stock, $0.001 par value	**The American Stock Exchange**
(Title of Class)	**(Name of Exchange on Which Registered)**

Securities Registered Pursuant to Section 12(g) of the Act:

Common Stock, $0.001 par value

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ¨ No x

The aggregate market value of the voting stock held by non-affiliates of the registrant, based upon the closing sales price of the common stock on December 31, 2002, was approximately $10,418,000 (based on the closing sale price of the common stock as reported by The American Stock Exchange on such date).

The number of outstanding shares of the registrant s common stock as of September 15, 2003 was 20,639,526.

DOCUMENTS INCORPORATED BY REFERENCE

None

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EXPLANATORY NOTE

This Amendment No. 2 (Amendment No. 2) supplements the Annual Report on Form 10-K for Cortex Pharmaceuticals, Inc. for the fiscal year ended June 30, 2003, as amended to date (the Report), by revising certain information contained in Items 1, 8 and 15 of the Report, and in Notes 1, 5 and 7 to the consolidated financial statements, and also attaches Exhibits 23.1, 31.1 and 31.2. No further revisions have been made to the previously filed Report.

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(Attached to this Amendment No. 2)

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INTRODUCTORY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Company intends that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements, which may be identified by words including anticipates, believes, intends, estimates, expects, and similar expressions include, but are not limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company s proposed products and (iv) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions regarding the Company s business and technology, which involve judgments with respect to, among other things, future scientific, economic and competitive conditions, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the control of the Company. Although the Company believes that the assumptions underlying the forward-looking statements are reasonable, actual results may differ materially from those set forth in the forward-looking statements. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as representation by the Company or any other person that the objectives or plans of the Company will be achieved.

PART I

Item 1. Business

Cortex Pharmaceuticals, Inc. (Cortex or the Company) was organized in 1987 to engage in the discovery, development and commercialization of innovative pharmaceuticals for the treatment of neurodegenerative diseases and other neurological and psychiatric disorders. Since 1993, the primary effort at Cortex has 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. Cortex is developing a family of chemical compounds known as AMPAKINE® compounds that enhance the activity of this receptor. Cortex believes 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. In 2001, on a worldwide basis these markets represented sales in excess of $40 billion. The Company s commercial development plan involves partnering with larger pharmaceutical companies for research, development, clinical testing, manufacturing and global marketing of its proposed products for those indications that require sizable, expensive Phase III clinical trials and very large sales forces to achieve significant market penetration. At the same time, Cortex plans to develop internally a selected set of indications, many of which will allow it to apply for Orphan Drug status. Such designation within the Food and Drug Administration is usually applied to products where the number of patients in the given disease category is less than 200,000 per year. These indications typically require more modest investment in the development stages, follow a quicker regulatory path, and involve a more concentrated sales reach to a few, selected medical centers in the United States. If the Company is successful in the pursuit of this operating strategy, it may be able to apply for a product registration for at least one Orphan Drug indication within a four year time frame. Cortex will continue to seek at least one more significant license agreement with a larger pharmaceutical company, while the Company prepares itself for potential entrance into the pharmaceutical market with its own product.

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In January 1999, the Company entered into a research collaboration and exclusive worldwide license agreement with NV Organon (Organon), a subsidiary of Akzo Nobel. The agreement grants Organon worldwide rights to develop and commercialize the Company s AMPAKINE technology for the treatment of schizophrenia and depression. In October 2000, the Company entered into a research collaboration and license agreement with Les Laboratoires Servier (Servier). The agreement, as amended in October 2002, will allow Servier to develop and commercialize the Company s 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.

Cortex continues to seek collaborative or licensing arrangements with other pharmaceutical companies. These arrangements may permit other applications of the AMPAKINE compounds to be advanced into later stages of clinical development and may provide access to the extensive clinical trials management, manufacturing and marketing expertise of such companies. The Company may not be able to secure such arrangements on favorable terms, or at all, and its products may not be successfully developed and approved for marketing by government regulatory agencies.

In the fiscal years ended June 30, 2003 and 2002, the Company s total operating expenses were approximately $6,421,000 and $7,487,000, respectively. Amounts for fiscal year 2002 include expenses for initiating the Phase II clinical study of the AMPAKINE CX516 in patients with mild cognitive impairment and certain technology access payments related to the Company s license of the AMPAKINE technology from the University of California.

Cortex is a development stage company and faces a number of risks in moving its technology through research, development and commercialization. Since its inception in 1987, the Company has never had revenues from commercial sales, has never been profitable on an annual basis and has incurred net losses approximating $45,863,000. Cortex does 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 licenses of the Company s technology. Even if the Company obtains funding, the pharmaceutical development and approval process is protracted and often the new drug candidates of companies such as Cortex s 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, the Company s competitors may develop and market superior drugs or assert intellectual property rights that impair the Company s ability to commercialize its drugs. As of yet, Cortex has not obtained FDA approval to market any of its products. All of these risks, and others, are described in Risk Factors starting on page 18.

In this annual report, the terms we, our, and us refer to Cortex Pharmaceuticals, Inc., a Delaware corporation. Our executive offices are located at 15231 Barranca Parkway, Irvine, California 92618, and our telephone number is (949) 727-3157. Our website is www.cortexpharm.com.

AMPA Receptor Program

In June 1993, Cortex licensed a new class of molecules and technology the AMPAKINE technology from the University of California. Cortex has subsequently been working to develop and patent new AMPAKINE molecules and to demonstrate efficacy and safety in a number of potential indications.

AMPAKINE compounds facilitate the activity of the AMPA receptor, which binds the neurotransmitter glutamate. The AMPAKINE compounds interact in a highly specific manner with the AMPA receptor in the brain, lowering the amount of neurotransmitter required to generate a response, and increasing the magnitude of the response to any given amount of glutamate. Cortex hopes that this selective amplification of the

normal glutamate signal will eventually find utility in the treatment of neurological diseases and disorders characterized by depressed functioning of brain pathways that utilize glutamate as a neurotransmitter.

It is well known that synaptic connections, including those that utilize glutamate, decline with age. Thus, disorders associated with aging may be amenable to treatment with AMPAKINE compounds. Two such disorders are mild cognitive impairment and Alzheimer s disease. Schizophrenia and other disorders that may involve neurotransmitter imbalances, including reduced levels of glutamate transmission, may also benefit from AMPA-receptor directed therapeutics. A study with AMPAKINE compounds in patients with schizophrenia indicated improvement in a number of symptoms also common to patients with Attention Deficit Hyperactivity Disorder (ADHD). The Company and its collaborators have obtained other encouraging preliminary results in animal models of depression, sexual dysfunction and stroke.

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One of the most compelling animal studies conducted to date with the AMPAKINE compounds involved an assessment of the effects on memory performance in middle-aged rats. A number of researchers have demonstrated that healthy middle-aged rats have significant deficits in memory performance when compared to younger animals. This provides an animal model for age-associated memory impairment in humans. In a study published in *Synapse*, the authors conducted research involving a maze task with middle-aged and young adult rats. The middle-aged rats showed striking deficits in performance when compared with the young adult animals. When given an AMPAKINE compound, the performance of the middle-aged rats improved to levels equivalent to those found in young animals.

Three human clinical safety studies have been completed with the AMPAKINE CX516 (AMPALEX) in healthy volunteers. In all three studies, CX516 was safe and well-tolerated on acute oral administration and, importantly, indicated statistically-significant positive effects on memory performance.

The initial study, conducted by AFB Parexel in Berlin, Germany, involved single administrations of drug or placebo to a total of 48 healthy young adult volunteers, ranging in age from 18 to 35. The trial was double-blinded and placebo-controlled, and included administering a single dose of drug in capsule form to each volunteer. Several dosages of drug were tested and at all dosage levels, the drug was safe and well-tolerated. In addition, analysis of psychological data revealed a highly statistically significant positive effect on a test of memory performance that involved recall of a list of nonsense syllables.

The second trial, at the same clinical site in Berlin, involved 30 healthy elderly volunteers, aged 65 to 76, each of whom was administered a single oral dose of drug or placebo. In this double-blinded trial, CX516 was again found to be safe and well-tolerated. The elderly volunteers were also given the same nonsense syllable memory test that had been given to the young volunteers in the first study. In the absence of drug, the elderly volunteers memory was substantially worse than that of the young volunteers. In the presence of drug, a statistically significant positive effect on memory performance was observed. Several of the elderly volunteers receiving the highest dosage of CX516 scored at or above the average score achieved by the young volunteers in the earlier study.

The third study, at the Karolinska Hospital in Stockholm, Sweden, involved administration of CX516 to healthy young adults under double-blind, placebo-controlled conditions. This five-day study involved administration of placebo on days 1, 4 and 5 and drug on days 2 and 3, with psychological testing conducted on each day. CX516 was safe and well-tolerated by all volunteers receiving drug, with no adverse events reported. Statistically significant improvements in performance on several measures of learning and memory were noted in the group that received CX516.

After these encouraging results, Cortex initiated a Phase I/IIa study in patients experiencing deficits of memory and cognition due to Alzheimer s disease. The double-blind, placebo-controlled dose escalation study, which was conducted at the National Institutes of Health in Bethesda, Maryland, involved administration of CX516 to an eventual total of 14 patients for up to 28 days. A preliminary analysis of the data indicates improvement in ADAS-cog and CIBIC plus, two measures used to detect medication induced changes in Alzheimer s disease patients. The ADAS-cog is an objective standard used for measuring changes in memory and cognition. The CIBIC plus is a subjective measure used by physicians to detect overall improvement in a patient s memory.

While the clinical testing of the AMPAKINE technology initiated by Cortex provided preliminary indications of desired effects on memory and cognition, psychological testing of patients with Alzheimer s disease is subject to a high level of variability. Full-scale Phase II studies designed to achieve significance on broad psychological scales will require larger numbers of patients. Cortex intends that further clinical studies of AMPAKINE compounds as a treatment for Alzheimer s disease will be conducted in collaboration with its corporate partner, Servier.

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In June 2000, Cortex received $247,000 from the Institute for the Study of Aging (the Institute), a non-profit foundation based in New York City and dedicated to the improvement in quality of life for the elderly. The funds provided support for the clinical trial conducted with Servier in patients with MCI, as explained more fully below. In the event that Cortex enters one of its AMPAKINE compounds into Phase III clinical studies as a treatment for Alzheimer s disease, Cortex has agreed to repay the funds to the Institute to allow them to financially assist other biotechnology companies.

In October 2000, the Company entered into a research collaboration and an exclusive license agreement with Servier. The agreements will enable Servier to develop and commercialize Cortex s proprietary AMPAKINE technology for the treatment of declines in cognitive performance associated with aging and of neurodegenerative diseases. The indications covered include, but are not limited to, Alzheimer s disease, MCI, sexual dysfunction, and the dementia associated with multiple sclerosis and Amyotrophic Lateral Sclerosis. The territory covered by the exclusive license excludes North America, allowing Cortex to retain commercialization rights in its domestic market. The territory covered by the agreement also excludes South America (except Argentina, Brazil and Venezuela), Australia and New Zealand. The agreement includes an up-front payment by Servier of $5,000,000, research support payments of approximately $2,000,000 per year through early December 2005 (subject to annual increases) and milestone payments, plus royalty payments on product sales, if any, in licensed territories. In October 2002, Servier agreed to provide Cortex an additional $4,000,000 of research support over a two-year period, in exchange for rights to the Cortex AMPAKINE compounds for the potential treatment of anxiety disorders, in Servier s licensed territories.

See Risk Factors *We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies* for a discussion of certain risks related to the development and commercialization of our products, including, without limitation, risks related to our clinical trials.

Mild Cognitive Impairment and Alzheimer s Disease

Impairment of memory and cognition is a significant health care problem that is growing as the elderly population continues to increase. While not fatal (except when associated with diseases such as Alzheimer s disease), the incidence and prevalence of cognitive deficits inevitably increase with age. Many elderly individuals are confined to nursing homes because of psychological disorientation and functional difficulties. Pharmaceuticals to alleviate deficits in memory and cognition could potentially enable these elderly individuals to remain independent longer, resulting in improved quality of life and substantial savings in health care costs. Cognitive deficit is also associated with a number of other neurological and neurodegenerative diseases, including autism, fragile X syndrome, multiple sclerosis, Amyotrophic Lateral Sclerosis and Huntington disease.

Although disease and physiological malfunctions may be the fundamental cause of severe mental decline, age itself is a contributory factor, with the human brain losing about 10% of its weight over a normal life span. In the cerebral cortex, a great deal of the communication between neurons is mediated by receptors for the neurotransmitter glutamate, including a subtype known as the AMPA receptor.

AMPA receptors and synapses decline in number with aging, on average by 25-30% between the ages of 25 and 65, making it more difficult for information to pass through and between areas of the cerebral cortex. Therefore a potential corrective approach to alleviate age-related cognitive deficits is to enhance the activity of the remaining functional AMPA receptors. AMPAKINE compounds amplify glutamate currents and have been shown to alleviate memory deficits in experiments in both elderly animals and humans.

In the aging population there is a continuum of cognitive decline. This continuum ranges from normal (for the general age group) to mild cognitive impairment (MCI) to probable Alzheimer s disease (AD) or other types of dementia.

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Patients with MCI currently represent the earliest clinically-defined group with memory impairment beyond that expected for normal individuals of the same age and education, but do not meet clinical criteria for AD. It is estimated that there are between 3 and 4 million people with MCI. The memory deficits in the MCI population are clinically discernable and can interfere with daily functioning. MCI patients also appear to have a greatly increased risk of developing AD. Whereas approximately 1-2% of the normal elderly population will be diagnosed with AD every year, 10-15% or more of MCI patients will progress to AD per year.

Alzheimer s disease is the most common destroyer of memory, currently afflicting some 4 million Americans and 12 million people worldwide. With the aging of our population, unless a treatment is found, the number of people in the U.S. with the disease is expected to reach 14 million by the middle of this century. According to the Alzheimer s Association, the U.S. society spends at least $100 billion a year on Alzheimer s disease at an average lifetime cost per patient of $174,000. Neither Medicare nor most private health insurance covers the long-term care more patients need. The impact of an effective treatment, even a symptomatic one, would be enormous.

It s in the early stages of Alzheimer s disease that Cortex believes AMPAKINE molecules may play a valuable role, enhancing the effectiveness of the brain cells that have not yet succumbed to the disease. This enhancement may help to alleviate the memory and cognitive deficits that make up the early symptoms.

There is also a possibility that treatment with AMPAKINE compounds may slow the progression of Alzheimer s disease. Brain cells, or neurons, require continued input from other brain cells to remain alive. As neurons die, other neurons begin to lose their inputs, hastening their own death. AMPAKINE compounds may slow the rate at which functional levels of input from other neurons are lost. In animal models, selected AMPAKINE compounds have been shown to increase the production of BDNF, which is a protein associated with the formation of synapses by neurons. This possible mode of action also may prove beneficial to patients with Alzheimer s disease, although it has not been demonstrated whether the same mechanism may produce similar results in humans.

In March 2001, a Food and Drug Association (FDA) advisory panel concluded that MCI is a distinct condition separate from Alzheimer s disease and a valid target for new therapies regardless of whether a new drug slows progression to dementia. The FDA indicated its willingness to approve a drug that can be shown to be safe and effective in improving memory. This decision represents a marked departure from the FDA s prior reluctance to approve such medications, encouraging Cortex in its pursuit of developing a drug that may treat memory disorders. Cortex has rights to issued patents in the United States, Mexico and Australia covering the use of any AMPA receptor modulating compounds to improve memory and cognition. During the fiscal year ended June 30, 2003, Cortex received a notice of allowance for a similar patent in Europe.

Together with Servier, Cortex conducted a cross-national study of the AMPAKINE technology as a potential treatment for MCI. This study was designed and conducted by a joint Cortex and Servier clinical team, in consultation with an International Scientific Advisory Committee (ISAC). A separate independent data safety monitoring board, commissioned by Cortex, monitored the safety aspects of this study in a blinded fashion for severe adverse events. The diagnostic procedures, as well as the primary and secondary outcome measures, were agreed upon by the ISAC composed of neurological experts and a prominent statistician from academic institutions in the United States and Europe. The majority of the study costs were funded by Servier, with initial funding provided by the Institute for the Study of Aging, a non-profit foundation supported by the Estee Lauder Trust.

The Phase II study began enrollment in March 2002 in the United States and several months later in five European countries. The last patient completed the study in mid-August 2003.

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This cross-national study used a randomized, double-blind, placebo-controlled, fixed-dose of CX516 with an objective of evaluating the efficacy and safety of the compound in patients with MCI. There were a total of 9 investigative sites in the United States and 22 sites across France, Belgium, the United Kingdom, Sweden and the Netherlands, making a total of 31 sites. One hundred seventy-five patients met the entry criteria for MCI and were randomized to receive CX516 (n = 84) or placebo (n = 91). Each patient received a fixed dose of three capsules of 300 mg of CX516 (900 mg) three times a day (2700 mg), or matching placebo capsules.

CX516 failed to meet the study s primary endpoint, improvements in the 15-item word list delayed recall. However, a subset review of the patients with the worst baseline memory impairment (the worst 25% of the patient population), showed substantial improvement with CX516 versus placebo on the 15- item word list delayed recall test. A review of the safety data showed a significant difference in patient withdrawals in the active treatment group, primarily due to gastrointestinal side effects, when compared to the placebo group. While there were a substantial number of adverse events in the active treatment group, only the gastrointestinal side effects were significantly different from those side effects attributed to the placebo group. There were no treatment-related serious adverse events in either the placebo or CX516 groups.

CX516 has a half-life of less than one hour and very low potency, making improvement in the primary endpoint for this study a difficult objective to achieve. This study was designed as a real world trial with dosages taken by patients who were ambulatory and at home. Consequently, when the patients would return to the clinic, the clinician could not control the elapsed time between dosing and the testing evaluations. Normally this may not have been a significant issue, given that upon multi-dosing, most drugs will reach an equilibrium, steady-state level in the therapeutic blood level range after a few days of dosing. However, with the very short half-live of CX516, such equilibrium levels likely were not achieved. The low potency of CX516 was affirmed in a recently completed primate study by Dr. Sam Deadwyler, Professor and Vice Chairman of the Department of Physiology and Pharmacology at Wake Forest University School of Medicine, which suggests that CX516 did not show any significant activity in their primate behavioral model of short term memory until the dose exceeded 20 mg/Kg. The dosage utilized in the cross-national MCI study was approximately 12 mg/Kg.

Neither Cortex nor Servier views the results from this MCI study as an indication that the AMPAKINE technology is flawed. Both companies have a large number of compounds with much greater potency and longer pharmacokinetic half-lives, which will be more appropriate for clinical development than the proof of concept compound, CX516. Both companies are proceeding diligently with the clinical development of two other AMPAKINE drugs, CX717 from Cortex and S-18986 from Servier.

Based on the Company s animal and clinical studies, Cortex believes that CX516 is a short acting drug that requires multiple administrations of relatively high doses per day to achieve and maintain the desired therapeutic effect. Therefore, Cortex does not intend to commercialize this compound. There are currently other studies underway with CX516 in fragile X syndrome, Alzheimer s disease and schizophrenia (as a combination with anti-psychotics). The Company is working with these investigators to reach a decision on how these clinical trials should proceed.

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Schizophrenia

The worldwide incidence of schizophrenia is approximately one percent of the population, regardless of ethnic, cultural or socioeconomic status. On any given day, approximately 100,000 of the estimated two million U.S. patients with schizophrenia are in public mental hospitals.

Schizophrenia typically develops in late adolescence or early adulthood and involves a collection of symptoms. These are generally characterized as *positive symptoms* (delusions and hallucinations), *negative symptoms* (social withdrawal and loss of emotional responsiveness) and *cognitive symptoms* (disordered thought and attention deficits).

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The first conventional anti-psychotics for schizophrenia were developed in the 1950s and 1960s. These drugs helped to reduce the positive symptoms of the disease and greatly reduced the need for chronic hospitalization. However, some of these drugs are characterized by troublesome and occasionally life-threatening side effects. One of the most common side effects of conventional anti-psychotics is EPS or extrapyramidal signs, which include restlessness and tremors. EPS side effects have a strong negative impact on quality of life and tend to lead to poor patient compliance with medication.

Since then, a new type of anti-psychotic agent, referred to as *atypical* due to the virtual lack of EPS side effects, has been developed. Clozapine was the first such drug. It was initially studied in the 1970s, but clinical trials were halted due to the risk of a fatal blood disorder known as agranulocytosis and a dose-dependent risk of seizures. Clozapine was reintroduced in the 1980s, with approval by the FDA for use in patients who cannot be adequately treated with conventional anti-psychotics, either because of lack of efficacy or side effects. Risperidone and olanzapine are other recent atypical anti-psychotics without agranulocytosis side effects.

The newer atypical agents achieve good control of positive symptoms, partial control of negative symptoms and better patient compliance with medication due to lower levels of EPS side effects. However, clinicians agree that there are still substantial side effects and that the cognitive symptoms of schizophrenia are not greatly improved by any available agent. The persistence of cognitive symptoms prevents many patients from successfully reintegrating into society.

Schizophrenia has long been thought to have its biochemical basis in an over-activity of dopamine pathways projecting into an area of the brain known as the striatum. More recently, a developing body of evidence suggests that schizophrenia also involves reduced activity of glutamate pathways projecting into the same area. Cortex began studying whether Ampakine compounds, which increase current flow through the AMPA subtype of glutamate receptor, might have relevance to the treatment of schizophrenia.

In late 1995, Cortex announced the discovery that an Ampakine compound reduced stereotypic behavior (mechanical repetition of posture or movement) in rats that had been injected with methamphetamine. Reduction of methamphetamine-induced stereotypic behavior is widely used for initial screening of anti-psychotic drugs. Scientists at the University of California, Irvine and Cortex have since extended this finding to include additional Ampakine molecules. Further, Cortex scientists have demonstrated that Ampakine compounds in combination with either conventional or atypical anti-psychotic drugs have additive or synergistic effects in this model system.

In January 1999, Cortex entered into an exclusive worldwide license agreement with Organon. The agreement will enable Organon to develop and commercialize Cortex s proprietary Ampakine technology for the treatment of schizophrenia. Under the agreement, Organon has rights to intellectual property that includes broad medical use patents covering the use of any AMPA receptor modulating compound to treat schizophrenia as a mono-therapy, or in combination with other anti-psychotic medications.

The agreement also included an option for Organon to expand its rights to the technology as a potential treatment for depression. Organon exercised that option in January 2001, thereby committing to specified spending on research in the field using Ampakine compounds.

The agreement with Organon provided an up-front payment of $2,000,000 and research support payments of approximately $3,000,000 per year for two years. The agreement also includes milestone payments and royalty payments on worldwide product sales, if any. Cortex believes that the agreement with Organon will provide an accelerated program to bring the Ampakine technology to market for schizophrenia and depression, if proven safe and effective in clinical trials.

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Shortly after signing the agreement with Organon, in April 1999 Cortex reported preliminary results from a study with CX516 in patients with schizophrenia being treated with clozapine. This Phase I/IIa clinical trial, conducted at Massachusetts General Hospital, was designed primarily as a safety study. Extensive testing also was included in an attempt to obtain a preliminary indication that CX516 may effect the psychological parameters that likely contribute to symptoms of the disease, particularly the cognitive symptoms that have thus far been resistant to treatment. The results indicate that CX516 is reasonably safe in combination with clozapine and improves performance on a number of tests of verbal learning, memory, problem solving and distractability. Interestingly, the improvements noted in CX516-treated patients appeared to persist for a period after cessation of treatment.

Further clinical testing of the AMPAKINE compounds in patients with schizophrenia is being conducted by the Company s corporate partner, Organon. In May 2000, Cortex achieved its first milestone under the related agreement when Organon selected a licensed compound to pursue in Phase I clinical testing, triggering a $2,000,000 payment to Cortex. In September 2001, Organon informed Cortex of its intent to continue development of the selected compound by entering Phase II clinical testing, triggering a second $2,000,000 milestone payment. Additional payments from the Organon agreement for schizophrenia will depend upon the results of the Phase II study.

In September 2001, Cortex received notice of a Phase II Small Business Innovative Research (SBIR) award for aproximately $770,000 from the National Institutes of Health to investigate the therapeutic potential of the AMPAKINE technology in schizophrenia. The goals of the related research plan include determining whether an AMPAKINE compound will improve negative symptoms, attention and memory. The research plan also hopes to assess the effects of an AMPAKINE compound on positive systems, anxiety and depressive symptoms. As of June 30, 2003, Cortex had received $500,000 from this two-year grant award, with the term of the grant award extended for an additional one-year period.

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Attention Deficit Hyperactivity Disorder

Attention Deficit Hyperactivity Disorder is the most commonly diagnosed psychological disorder of children. The National Institute of Mental Health (NIMH) estimates that ADHD affects three to five percent of school-age children, with about one child in every classroom in the U.S. in need of help for this disorder. According to the NIMH, national public school spending on behalf of students with ADHD may have exceeded $3 billion in 1995.

Symptoms of ADHD include an inability to sustain attention and concentration, along with developmentally inappropriate levels of activity, distractability and impulsivity. Children with the disorder may have functional impairment across multiple settings including home, school and peer relationships. ADHD has also been linked to long-term adverse effects on academic performance, vocational success and social and emotional development. These effects not only impact the individual patients, but also their families, schools and communities. For many, the symptoms and impact of the disorder continue into adulthood.

Psychostimulants, including amphetamine, methylphenidate and pemoline, represent the most widely researched and commonly prescribed treatments for the disorder. One theory suggests that ADHD results from difficulties in inhibiting responses to internal and external stimuli. Evidence suggests that those areas of the brain thought to be involved in planning, foresight, and consideration of alternative responses may be under-stimulated in patients with ADHD. Stimulant medication may work on these areas of the brain to increase neural activity to more normal levels.

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Because of the availability and frequent prescribing of psychostimulants, concerns over their potential overuse and abuse have intensified. Along with the abuse potential, treatments with psychostimulants may result in side effects. According to the National Institutes of Health, some children on these medications may lose weight, have less appetite and temporarily grow more slowly. Others may experience problems falling asleep. Given the lack of consistent improvement beyond the disorder s core symptoms and the deficit of long-term studies, the need remains for additional testing with medications and behavioral treatments.

In April 1999, the Company reported preliminary results from a study with the AMPAKINE CX516 in patients with schizophrenia being treated with clozapine. The results noted in CX516-treated patients included improved performance on several tests of memory, problem solving and distractability, as well as a clinical improvement in attention symptoms that are also common to patients with ADHD. Based upon these results, the Company believes that AMPAKINE compounds may represent a novel, non-controlled (not regulated by the Drug Enforcement Agency) approach for treating ADHD patients.

In April 2000, the Company entered an option agreement with Shire Pharmaceuticals Group, plc (Shire), under which Shire initiated a Phase II double-blind, placebo-controlled study of Cortex s AMPAKINE CX516 for the treatment of ADHD. Enrollment in the study began in the summer of 2001, with Shire responsible for all of the costs of the trial. In exchange for the option, Cortex received $130,000; Shire also purchased 254,353 shares of Cortex common stock for $870,000.

Shire had the right to convert its option into an exclusive worldwide license for the AMPAKINE technology for ADHD. Upon exercise, Cortex would have received a license fee, milestone payments based on successful clinical and commercial development, research support for additional AMPAKINE compounds and royalties on sales.

In May 2002, Shire made a business decision to abruptly terminate the Phase II study of CX516 in adult patients with ADHD. At the time of the decision to immediately stop all treatments, 72 patients out of a planned 110 patient study target had been enrolled. Only 45 patients had completed the 28-day course of treatment required by the study design. Because the study design was broken by the sudden cessation of all treatments and only 40% of the patients completed the full treatment plan, the data from the study could not be properly analyzed. In June 2002, Shire elected not to exercise its option for use of the AMPAKINE technology in ADHD. Cortex still believes that the potential for the use of AMPAKINE compounds as a treatment for ADHD exists and is seeking other partners to pursue this possibility.

See Risk Factors *We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies* for a discussion of certain risks related to the development and commercialization of our products, including, without limitation, risks related to our clinical trials.

Stroke

A stroke occurs when a blood clot blocks a blood vessel or artery, or when a blood vessel breaks and interrupts blood flow to the brain. When a stroke occurs, brain cells within the immediate area of damage usually die within minutes to a few hours. When brain cells die, control of functions such as speech, movement and memory may be lost.

A stroke can happen to anyone, although the risk increases significantly with age. According to the National Stroke Association, two-thirds of all strokes happen to people over the age of 65, with the risk doubling each decade past age 55.

Treatment of stroke victims represents a critical unmet need. The National Stroke Association estimates that there are nearly four million people in the U.S. who have survived a stroke and are living with the after-effects.

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General recovery guidelines indicate that 35% of stroke survivors recover nearly completely, or with minor impairments. Of the remaining 65% of survivors, 40% suffer moderate to severe impairments, 10% require specialized care in a nursing home or other long-term care facility and 15% die shortly following the stroke.

Preclinical experiments conducted by Kevin Lee, Ph.D. at the University of Virginia and by two pharmaceutical companies have demonstrated that the AMPAKINE CX516 can be safely administered to animals under mimicked stroke-like conditions. Additionally, research at Cortex suggests that AMPAKINE compounds may be neuroprotective AMPAKINE treatment may provide protection to at-risk neurons adjacent to the area of damage following a stroke.

AMPAKINE compounds also may improve post-stroke recovery. Nerve cells depend upon active stimulation or communication to maintain function. After a stroke, many neurons lose connections with other cells. Patients must try to recover function by engaging new pathways of nerve cell communication. AMPAKINE compounds, which enhance communication between nerve cells, may be ideal for the stroke recovery process.

In May 1999, Cortex received notice of a Phase I SBIR award of $100,000 from the National Institutes of Health to investigate the AMPAKINE technology as a potential new stroke therapy. Subsequently, in October 2000 Cortex received notice of a Phase II SBIR award of up to $1,074,000 to continue its research.

The goals of the research plan include determining if an AMPAKINE compound administered in advance can reduce damage to neurons in an animal model of stroke; and to determine if the compound reduces damage to the memory of the animals. An AMPAKINE compound will also be administered after the stroke to determine if there is an improved recovery of memory function. As of June 30, 2003, Cortex had received approximately $655,000 from this three-year grant award, with the term of the project extended for a one-year period. Research of the AMPAKINE technology as a treatment for stroke, beyond that funded by the SBIR grant, will depend upon the Company s financial resources.

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Fragile X and Autism

Fragile X is an inherited disorder that represents the most common cause of inherited mental retardation. The disorder affects approximately 60,000 to 80,000 patients in the U.S. alone. Symptoms of fragile X syndrome include mental impairment ranging from learning disabilities to mental retardation, attention deficit and hyperactivity, anxiety and unstable mood and autistic-like behaviors.

Males are typically more severely affected by fragile X syndrome than females. Although most males with fragile X syndrome have mental retardation, only one-third to one-half of females with the disorder have significant intellectual impairment; the rest have either normal intelligence or learning disabilities. Emotional and behavioral problems are common in both sexes. There are no current therapeutic treatments for the disorder, although medications are used to treat some symptoms.

Autism is a complex developmental disability that typically appears during the first three years of life. The result of a neurological disorder that affects the functioning of the brain, autism and its associated behaviors have been estimated to occur in as many as 2 to 6 in 1,000 individuals. The disability is four times more prevalent in males than in females.

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Autism impacts the normal development of the brain in the areas of social interaction and communication skills. Children and adults with autism typically have difficulties in verbal and nonverbal communication, social interactions, and leisure or play activities. Persons with autism may exhibit repeated body movements, unusual responses to people or attachments to objects, and resistance to changes in routines. Individuals also may experience heightened sensitivities of sight, hearing, touch, smell and taste. There are currently no approved therapeutic treatments for autism, although early behavioral intervention dramatically improves outcome.

Recent scientific research has led to an improved understanding of fragile X syndrome and autism. A number of scientists have suggested that the use of a drug to enhance glutamate transmission may be beneficial. AMPAKINE compounds, which have demonstrated enhanced glutamate transmission, may therefore serve as potential new therapeutics.

Imaging studies demonstrate that areas of the brain that are extremely rich in glutamate transmission are less active in autistic patients. Molecular studies suggest that although genes involved in the AMPA-type glutamate receptor are more active in autistic patients, the density of AMPA-type glutamate receptors is decreased. Taken together, these facts suggest that enhancing AMPA receptor activity may be beneficial in autistic patients.

The scientific logic for using an AMPA receptor modulator in fragile X is more complex but equally compelling. The fragile X genetic defect results in the reduction or absence of an important protein, FMRP. FMRP is thought to play an important role in allowing normal levels of AMPA receptor proteins to be made. Increasing the activity of AMPA receptors with an AMPAKINE may overcome the reduced number of AMPA receptors produced by the reduced level of FMRP protein.

In April 2002, Cortex announced that it is collaborating with several research organizations to conduct a Phase II clinical study to evaluate the AMPAKINE CX516 as a potential treatment for fragile X syndrome and autism. The study design is a randomized double-blind, placebo controlled trial with four weeks of treatment. Outcome measures will include testing in attention and executive function, spatial and verbal/auditory memory, language domain and behavior domain. Patient enrollment began in May 2002 and is anticipated to continue over a two-year period.

The FRAXA Research Foundation is providing funding for the trial at Rush-Presbyterian-St. Luke s Medical Center in Chicago, and Cortex is providing study medication (CX516 and placebo capsules). The Child and Adolescent Psychiatry Department at the University of Chicago will also participate in the study along with The Mind Institute at the University of Davis Medical Center.

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Narcolepsy and Other Sleep Disorders

Narcolepsy represents a disabling neurological disorder involving excessive daytime sleepiness and periodic irresistible sleep attacks of sudden onset and brief duration. The number and severity of symptoms vary widely among individuals with the disorder, with symptoms generally beginning between the ages of 15 and 30. Prevalence of narcolepsy in the U.S. is under 200,000. The disorder is known to occur in equal frequency in both sexes and to affect all ethnic populations.

According to the National Institute of Neurological Disorders and Stroke (NINDS), patients with narcolepsy experience sleep attacks that can last for up to 30 minutes, regardless of the amount or quality of the prior night s sleep. The sleep attacks may occur at work, social events, while eating, talking and driving, and in other similarly inappropriate circumstances.

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There is currently no cure for the disorder, although the symptoms may be controlled with behavioral and medical therapy. The therapeutic focus is to promote and enhance wakefulness and counteract excessive daytime sleepiness. The Company believes that AMPAKINE compounds may be useful in treating day time sleepiness, which is a key treatment for individuals with narcolepsy.

Sleep disorders represent a broad range of illnesses arising from many causes, including abnormalities in physiological functions during sleep, abnormalities of the biological clock and sleep disturbances that are induced by factors outside of the sleep process.

According to the National Sleep Foundation, over the past century, society has reduced its average asleep time by 20 percent and, in the past 25 years, added a month to its average annual work/commute time. When the body is deprived of the sleep that it needs, the ability to concentrate or perform even simple tasks declines, and productivity suffers.

An internal biological clock in the brain regulates our sleep needs and patterns. Almost everyone s clock is set for sleep at night, especially in the early morning hours between midnight and dawn. When our lives force us to work against our biological clocks, sleep problems are unavoidable.

The National Sleep Foundation estimates that 20 percent of American employees work non-traditional schedules. For these workers, getting enough sleep is a common problem.

Dr. Sam Deadwyler, Professor and Vice Chairman, Department of Physiology and Pharmacology at Wake Forest University School of Medicine, as part of a grant received from the Defense Advanced Research Projects Agency (DARPA) has studied the effects of sleep deprivation on cognitive performance and associated brain imaging changes in primates (to be published). Primates were trained to a high level of successful performance in a visual delayed-match-to-sample task. The animals were then individually sleep-deprived for 30-36 hours before being re-tested. Performance accuracy on the task was significantly reduced by 15-25%, and reaction times slowed by at least 50% in all monkeys as a result of the sleep deprivation. In a previous study using this model, Cortex s AMPAKINE CX516 completely reversed the effects of sleep-deprivation on performance at a dose of 40 mg/Kg.

Based upon these results, the Company initiated a single dose, double blind, placebo controlled, crossover design clinical study to test the ability of selected doses of CX516 or placebo to partially reverse the effects of sleep deprivation in young healthy adult male volunteers after 31 hours without sleep. Funded by DARPA, this study was performed in July 2003 at the Medical University of South Carolina by Dr. Mark S. George, Distinguished Professor of Psychiatry, Radiology and Neurology. Each of the 10 young healthy men were administered three doses of CX516, 10 mg/Kg, 20 mg/Kg and 30 mg/Kg. While CX516 showed a positive dose-related response on performance deficits, the 30 mg/Kg dose produced approximately a 30% improvement on performance after sleep deprivation. In Dr. Deadwyler s primate study, 40mg/Kg of CX516 were required to totally reverse the effects of sleep deprivation. In this first proof of concept study with CX516 in sleep deprivation, there was a favorable safety profile with no serious adverse events.

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In November 2003, at the Annual Society of Neuroscience Meeting, Dr. Deadwyler reported the results from a new sleep deprivation study in primates with the more potent AMPAKINE CX717. The results suggested that with CX717, a single dose of 0.5 to 1.5 mg/Kg produced an optimal response on short term memory, which would be the equivalent of approximately 75-100 mg per day in an elderly patient. Cortex has accelerated its development of CX717 and anticipates initiating clinical development of this compound beginning in the second calendar quarter of 2004.

Expansion to the use of AMPAKINE compounds to the treatment of narcolepsy may be possible. Narcolepsy represents an Orphan Drug indication that would reduce both the cost and time to market for a potential therapeutic agent from Cortex.

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Manufacturing

Cortex has no experience or capability to either manufacture bulk quantities of the new compounds that it develops, or to produce finished dosage forms of the compounds, such as tablets or capsules. Cortex relies, and presently intends to rely, on the manufacturing and quality control expertise of contract manufacturing organizations or current and prospective corporate partners. There is no assurance that the Company will be able to enter into manufacturing arrangements to produce bulk quantities of its compounds on favorable financial terms. There is however, substantial availability of dosage form manufacturing capability in the U.S. pharmaceutical industry that the Company believes that it can readily access.

Marketing

The Company has no experience in the marketing of pharmaceutical products and does not anticipate having the resources to distribute and broadly market any products that it may develop for indications such as Alzheimer s disease and schizophrenia. The Company will therefore continue to seek commercial development arrangements with other pharmaceutical companies for its proposed products for those indications that require significant sales forces to effectively market. In entering into such arrangements, the Company may seek to retain the right to promote or co-promote products for certain indications in North America. The Company s worldwide licensing agreement with Organon (see Note 5 of Notes to Financial Statements) does not provide Cortex with co-promotional rights. With respect to Orphan Drugs, the Company may distribute and market such products directly. There is no assurance that the Company will be able to enter into marketing arrangements in connection with its other licensing activities, or that marketing rights will lead to greater revenues for the Company.

Technology Rights

In 1993, Cortex entered an agreement with the Regents of the University of California, under which Cortex secured exclusive commercial rights to AMPA-receptor modulating technology and compounds (the AMPAKINE technology) for the treatment of deficits of memory and cognition. The relationship later was expanded to include additional agreements for other indications. The Company paid an initial license fee and is obligated to make additional payments, including license maintenance fees and patent expense reimbursements creditable against future royalties, over the course of initiating and conducting human clinical testing and obtaining regulatory approvals. When and if sales of licensed products commence,

the Company will pay royalties on net sales. During the fiscal year ended June 30, 2003, Cortex amended the agreement with the Regents of the University of California to exclude the treatment of disease areas outside of the Central Nervous System that the Company would not have the resources nor the capability to develop in a timely manner.

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Patents and Proprietary Rights

The Company is aggressively pursuing patent protection of its technologies. Cortex owns or has exclusive rights (within its areas of product development) to approximately 40 issued or allowed U.S. and foreign patents and has a number of additional U.S. patent applications and their international counterparts pending.

In 1998, Cortex received a United States patent that contained a broad claim for any AMPA-modulating compound to treat schizophrenia. Under the agreements with the Regents of the University of California (the University), Cortex has exclusive rights to AMPAKINE compounds for all applications covered by the University s patent rights, other than endocrine modulation, and the treatment of sexual dysfunction in North and South America. Cortex s rights are contingent upon it making certain minimum annual payments to the University, meeting certain milestones, and diligently seeking to commercialize the underlying technology.

In April 1999, Cortex received a patent that covers the Company s AMPAKINE compounds as well as compounds made by others for the treatment of memory and cognition. This patent allows Cortex and its licensees to exclude others in the United States from making and selling AMPA-receptor modulating compounds for the treatment of memory or dementia, including Alzheimer s disease. The Company believes that the coverage also extends to psychiatric conditions with cognitive disturbances including depression, obsessive compulsive disorder, attention deficit disorder, and phobic disorders. Similar patents have issued to Cortex in Mexico, Australia and New Zealand. In April 2003, Cortex announced the allowance of a similar patent by the European Patent Office. These patents issued to the University of California and rights to the patents are licensed to Cortex.

There is no assurance that patents, whether already issued or issuing in the future in connection with current or future patent applications, will afford effective protection against competitors with similar technology. There is also no assurance that any patents issued or licensed to Cortex will not be infringed upon or designed around by others. Further, since issuance of a patent does not guarantee the right to practice the claimed invention, there is no assurance that others will not obtain patents that the Company would then need to license or design around in order to practice its patented technologies, or that Cortex would be able to obtain licenses that might be required to practice these technologies due to patents of others on reasonable terms. Additionally, any unpatented manufacture, use or sale of the Company s technology, processes or products may infringe on patents or proprietary rights of others, and the Company may be unable to obtain licenses or other rights to these other technologies that may be required for commercialization of the Company s proposed products or processes.

Cortex relies to a certain extent upon unpatented proprietary technology and may determine in some cases that its interests would be better served by reliance on trade secrets or confidentiality agreements rather than patents. No assurance is made that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to or disclose such technology. In addition, there is no assurance that Cortex can meaningfully protect its rights in such unpatented proprietary technology or that others will not wrongfully obtain such technology.

If Cortex is unable to obtain strong protection of its proprietary rights in its products or processes prior to or after obtaining regulatory clearance, whether through patents, trade secrets or otherwise, competitors may be able to market competing products by obtaining regulatory clearance through demonstration of equivalency to the Company s products, without being required to conduct the same lengthy clinical tests conducted by the Company.

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Government Regulation

In order to test, produce and market human therapeutic products in the United States, mandatory procedures and safety standards established by the FDA must be satisfied. Obtaining FDA approval is a costly and time-consuming process. Cortex has initiated Phase I and early Phase II testing in the U.S. and Europe, primarily with the assistance of clinical collaborators and its corporate partners, Organon and Servier. Some clinical trials were and are performed in the U.S. under Notices of Claimed Investigational Exemption for a New Drug (IND) filed with the FDA by the Company s clinical collaborators. Cortex filed an IND for the AMPAKINE CX516 in the name of the Company in the fall of 2000. It is Cortex s intent that Organon, Servier or another pharmaceutical company partner or partners that the Company is seeking, will pursue other required regulatory approvals to conduct further clinical testing. Cortex intends to file other IND s for additional compounds to facilitate the development of its Orphan Drug strategy.

Clinical trials are normally conducted in three phases. Phase I trials are concerned primarily with safety of the drug, involve fewer than 100 subjects, and may take from six months to over a year. Phase II trials normally involve a few hundred patients. Phase II trials are designed to demonstrate effectiveness and to determine optimal dosing in treating or diagnosing the disease or condition for which the drug is intended. Short-term side effects and risks in people whose health is impaired also may be examined. Phase III trials may involve up to several thousand patients who have the disease or condition for which the drug is intended, to approximate more closely the conditions of ordinary medical practice. Phase III trials also are designed to clarify the drug s benefit-risk relationship, to uncover less common side effects and adverse reactions, and to generate information for proper labeling of the drug. The FDA receives reports on the progress of each phase of clinical testing, and may require the modification, suspension, or termination of clinical trials if an unwarranted risk is presented to patients. The FDA estimates that the clinical trial period of drug development can take up to ten years, and averages five years. With certain exceptions, once clinical testing is completed, the sponsor can submit a New Drug Application (NDA) for approval to market a drug. The FDA s review of an NDA can also be lengthy.

Therapeutic products that may be developed and sold by the Company outside the United States will be subject to regulation by the various countries in which they are to be distributed. In addition, products manufactured in the United States that have not yet been cleared for domestic distribution will require FDA approval in order to be exported to foreign countries for distribution there.

There is no assurance that any required FDA or other governmental approval will be granted or, if granted, will not be withdrawn. Governmental regulation may substantially delay or prevent the marketing of the Company s proposed products, or cause the Company to undertake additional procedures, which may be both costly and lengthy, and thereby furnish a competitive advantage to the competitors of the Company or its licensees.

Cortex plans to seek additional financing to support its development of selected AMPAKINE compounds for Orphan Drug indications. Without obtaining shareholder approval for such further issuance of securities, Cortex may be severely restricted in its overall development. The Company would be dependent upon its sub-licensees and would be unable to maintain its current core technical and management capabilities. Under such circumstances, the Company would be dependent upon entering into partnerships or other collaborative arrangements with third parties with the required resources to obtain the needed approvals. Along with its licensing agreements with Organon and Servier, Cortex intends to enter into license or other arrangements with other pharmaceutical companies under which those companies would conduct the required clinical trials and seek FDA approval for most or all of its proposed products. There is no assurance that Cortex will be able to enter into such arrangements on favorable terms, or at all, or that such arrangements will ultimately result in obtaining the necessary governmental approvals.

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Competition

The pharmaceutical industry is characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including both major pharmaceutical companies and specialized biotechnology companies, are engaged in activities similar to those of Cortex. A large number of drugs intended for the treatment of Alzheimer s disease, MCI, schizophrenia, depression, ADHD and other neurological and psychiatric diseases and disorders are on the market or in the later stages of clinical testing. For example, approximately 15 drugs are in development in the U.S. for schizophrenia and over 25 drugs are under clinical investigation in the U.S. for the treatment of Alzheimer s disease. Some of the Company s competitors have substantially greater financial and other resources and larger research and development staffs. Larger pharmaceutical company competitors also have significant experience in preclinical testing, human clinical trials and regulatory approval procedures.

In addition, colleges, universities, governmental agencies and other public and private research organizations will continue to conduct research. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect license fees, milestone payments and royalties in exchange for license rights to technology that they have developed, some of which may be directly competitive with that of the Company.

The Company expects technological developments in the neuropharmacology field to continue to occur at a rapid rate and expects that competition will remain intense as those advances continue. Based on the technical qualifications, expertise and reputations of its Scientific Directors, consultants and other key scientists, the Company believes that its operating strategy to develop AMPAKINE compounds for the treatment of selected Orphan Drug indications and to out-license the technology to larger pharmaceutical companies for major chronic indications is appropriate.

Product Liability Insurance

The clinical testing, manufacturing and marketing of the Company s products may expose the Company to product liability claims, against which the Company maintains liability insurance. Although the Company has never been subject to a product liability claim, there is no assurance that such claims will not be brought in the future, that the coverage limits of the Company s insurance policies will be adequate or that one or more successful claims brought against the Company would not have a material adverse effect upon the Company s business, financial condition and results of operations.

Employees

As of June 30, 2003, Cortex had 20 full-time employees and one part-time employee and had engaged one part-time DVM-level and three part-time Ph.D.-level scientific consultants. Of the 20 full-time employees, 14 were engaged in research and development, of which 8 were Ph.D.-level or equivalent, and 6 were engaged in management and administrative support. The Company also sponsors a substantial amount of research in academic laboratories, primarily at the University of California, Irvine.

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Risk Factors

In addition to the other matters set forth in this Annual Report on Form 10-K, our continuing operations and the price of our common stock are subject to the following risks:

Risks related to our business

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

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

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

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

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

- the results of our clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the ability to obtain funding under contractual and licensing agreements;
- the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property; and

our success in entering into collaborative relationships with other parties.

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

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our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products that we otherwise would not relinquish. If adequate funds are not available, we could lose our key employees and might have to delay, scale back or eliminate one or more of our research and development programs, which would impair our future prospects. In addition, we may be unable to meet our research spending obligations under our existing licensing agreements and may be unable to continue our business operations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks related to our industry

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

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

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

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

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

The clinical testing, manufacturing and marketing of our products may expose us to product liability claims. We maintain liability insurance with coverage limits of $5 million per occurrence and $5 million in the annual aggregate. We have never been subject to a product liability claim, and we require each patient in our clinical trials to sign an informed consent agreement that describes the risks related to the trials, but we cannot assure you that the coverage limits of our insurance policies will be adequate or that one or more successful claims brought against us would not have a material adverse effect on our business, financial condition and result of operations. Further, if one of our AMPAKINE compounds is approved by the FDA for marketing, we cannot assure you that adequate product liability insurance will be available, or if available, that it will be available at a reasonable cost. Any adverse outcome resulting from a product liability claim could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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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 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.

Other risks

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

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

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

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

Upon effectiveness of the registration statement that we are required to file in connection with our January 2004 private placement, an additional 6,909,091 shares will become freely tradable without restriction. If all outstanding warrants and options are exercised prior to their expiration, approximately 13.1 million additional shares of common stock could become freely tradable without restriction. Sales of substantial amounts of common stock in the public market could adversely affect the prevailing market price of our common stock.

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

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

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PART II

Item 8. Financial Statements and Supplementary Data

The financial statements of the Company and other information required by this item are set forth herein in a separate section beginning with the Index to Financial Statements on page F-1.

PART IV

ITEM 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K

(a) List of documents filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Financial Statements on page F-1, where these documents are listed.

(2) Financial Statement Schedules

The financial statement schedules have been omitted because the required information is not applicable, or not present in amounts sufficient to require submission of the schedules, or because the information is included in the financial statements or notes thereto.

(3) Exhibits

See (c) below.

(b) Reports on Form 8-K during the fourth quarter:

The Company furnished the press release announcing its financial results for the fiscal quarter ended March 31, 2003 to the Securities and Exchange Commission in a report on Form 8-K dated May 15, 2003.

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(c) Exhibits

Exhibit Number	Description
3.1	Restated Certificate of Incorporation dated April 11, 1989, as amended by Certificate of Amendment on June 27, 1989, by Certificate of Designation filed April 29, 1991, by Certificate of Correction filed May 1, 1991, by Certificate of Amendment of Certificate of Designation filed June 13, 1991, by Certificate of Amendment of Certificate of Incorporation filed November 12, 1992, by Certificate of Amendment of Restated Certificate of Incorporation filed January 11, 1995, by Certificate of Designation filed December 8, 1995, by Certificate of Designation filed October 15, 1996, and by Certificate of Designation filed June 4, 1997, by Certificate of Amendment of Restated Certificate of Incorporation filed December 21, 1998, and by Certificate of Designation filed February 11, 2002, incorporated by reference to Exhibit 3.1 of the Amendment No. 1 to Registration Statement on Form 8-A, No.001-16467, filed February 15, 2002.
3.2	By-Laws of the Company, as adopted March 4, 1987, and amended on October 8, 1996, incorporated by reference to Exhibit 3.2 to the Company s Annual Report on Form 10-KSB filed October 15, 1996.
3.3	Certificate of Amendment of Restated Certificate of Incorporation filed December 15, 2003, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-Q as filed on February 12, 2004.
4.1	Rights Agreement, dated as of February 8, 2002, between the Company and American Stock Transfer & Trust Company, which includes as Exhibit A thereto a form of Certificate of Designation for the Series A Junior Participating Preferred Stock, as Exhibit B thereto the Form of Rights Certificate and as Exhibit C thereto a Summary of Terms of Stockholder Rights Plan, incorporated by reference to Exhibit 4.2 to the Company s Amendment No. 1 to Registration Statement on Form 8-A, No. 001-16467, filed February 15, 2002.
10.2	Consulting Agreement, dated October 30, 1987, between the Company and Carl W. Cotman, Ph.D. *
10.3	Consulting Agreement, dated as October 30, 1987, between the Company and Gary S. Lynch, Ph.D. *
10.31	License Agreement dated June 25, 1993, as amended May 28, 2003, between the Company and the Regents of the University of California, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-Q filed February 12, 2004. (Portions of this Exhibit are omitted and were filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934).
10.44	Lease Agreement, dated January 31, 1994, for the Company s facilities in Irvine, California, incorporated by reference to Exhibit 10.44 of the Company s quarterly report on Form 10-QSB filed May 16, 1994.
10.49	Settlement Agreement between the Company and Alkermes, Inc., dated October 5, 1995, incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-KSB filed October 13, 1995. (Portions of this Exhibit are omitted and were filed separately with the Secretary of the Commission pursuant to the Company s Application requesting confidential treatment under Rule 406 of the Securities Act of 1933).
10.60	Amended and Restated 1996 Stock Incentive Plan, incorporated by reference to the same numbered exhibit to the Company s quarterly report on Form 10-Q as filed on November 14, 2002.
10.64	Research and Collaboration and License Agreement between the Company and N.V. Organon, dated January 13, 1999, incorporated by reference to Exhibit 10.64 of the Company s quarterly report on Form 10-QSB as filed on February 16, 1999. (Portions of this Exhibit were omitted and filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934.)
10.65	Amendment No. 1 to the Lease Agreement for the Company s facilities in Irvine, California, dated February 1, 1999, incorporated by reference to the same number Exhibit to the Company s Annual Report on Form 10-KSB filed September 28, 1999.
10.67	Collaborative Research, Joint Clinical Research and Licensing Agreements with Les Laboratoires Servier dated October 13, 2000, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-QSB filed November 14, 2000. (Portions of this Exhibit were omitted and filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 24b-2 of the Securities Act of 1934).

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Exhibit Number	Description
10.69	Employment agreement dated May 17, 2000, between the Company and James H. Coleman, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-QSB filed February 12, 2001.
10.70	Severance agreement dated October 26, 2000, between the Company and Maria S. Messinger, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-QSB filed February 12, 2001.
10.71	Employment agreement dated June 5, 1995, between the Company and Gary A. Rogers, Ph.D., incorporated by reference to the same numbered exhibit to the Company s Annual Report on Form 10-K filed October 15, 2002.
10.73	Amendment dated October 3, 2002 to the Collaboration Research Agreement with Les Laboratoires Servier dated October 13, 2000, incorporated by reference to the same numbered exhibit to the Company s Annual Report on Form 10-K filed October 15, 2002.
10.74	Employment agreement dated October 29, 2002 between the Company and Roger G. Stoll, Ph.D., incorporated by reference to the same numbered exhibit to the Company s quarterly report on Form 10-Q as filed on November 14, 2002.
10.75	Securities Purchase Agreement dated August 21, 2003, by and among Cortex Pharmaceuticals, Inc. and the investors named therein, including the Registration Rights Agreement attached as Exhibit A thereto and a form of Common Stock Purchase Warrant attached as Exhibit C thereto, incorporated by reference to the same numbered exhibit to the Company s Report on Form 8-K filed August 22, 2003.
10.76	Amendment dated April 8, 2003 to the employment agreement dated October 29, 2002 between the Company and Roger G. Stoll, Ph.D.**
10.77	Amendment dated December 16, 2003 to the Collaboration Research Agreement with Les Laboratoires Servier dated October 13, 2000, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-Q as filed on February 12, 2004. (Portions of this Exhibit are omitted and were filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 246-2 of the Securities Exchange Act of 1934.)
21	Subsidiaries of the Registrant, incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-KSB filed October 13, 2000.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24	Power of Attorney.**
31.1	Certification by Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a), As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a), As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **

* Incorporated by reference to the same numbered exhibit of the Company s Registration Statement on Form S-1, No. 33-28284, effective on July 18, 1989.

** Incorporated by reference to the same numbered exhibit to the Company s Annual Report on Form 10-K for the period ended June 30, 2003 filed with the Commission on September 19, 2003.

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Signatures

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this amendment no. 2 to its Annual Report on Form 10-K for the fiscal year ended June 30, 2003, to be signed on its behalf by the undersigned, thereunto duly authorized.

CORTEX PHARMACEUTICALS, INC.

Date: February 27, 2004

By: /s/ Roger G. Stoll, Ph.D.

Roger G. Stoll, Ph.D.

Chairman, President and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this amendment no. 2 to Annual Report on Form 10-K for the fiscal year ended June 30, 2003, has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Roger G. Stoll, Ph.D. Roger G. Stoll, Ph.D.	President, Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	February 27, 2004
/s/ Maria S. Messinger Maria S. Messinger	Chief Financial Officer (Principal Financial and Accounting Officer)	February 27, 2004
* Robert F. Allnutt	Director	February 27, 2004
* Charles J. Casamento	Director	February 27, 2004
* Carl W. Cotman, Ph.D.	Director	February 27, 2004
*	Director	February 27, 2004

M. Ross Johnson, Ph.D.

* By: /s/ Roger G. Stoll, Ph.D.

Roger G. Stoll, Ph.D.

Attorney-in-Fact

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Report of Ernst & Young LLP, Independent Auditors

The Stockholders and Board of Directors

Cortex Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Cortex Pharmaceuticals, Inc. (the Company) as of June 30, 2003 and 2002, and the related statements of operations, stockholders equity (deficit) and cash flows for the years ended June 30, 2003, 2002 and 2001. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cortex Pharmaceuticals, Inc. at June 30, 2003 and 2002, and the results of its operations and its cash flows for the three years then ended, in conformity with accounting principles generally accepted in the United States.

As discussed in Note 1 to the financial statements, in 2001 the Company changed its revenue recognition policy.

/s/ Ernst & Young LLP

San Diego, California

July 25, 2003,

except for the fourth

paragraph of footnote 1

and footnote 11, for

which the date is

August 21, 2003

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Cortex Pharmaceuticals, Inc.

BALANCE SHEETS

	June 30, 2003	June 30, 2002
Assets		
Current assets:		
Cash and cash equivalents	$ 1,125,054	$ 1,849,009
Restricted cash	83,411	180,886
Accounts receivable	428,451	115,472
Other current assets	210,539	350,872
Total current assets	1,847,455	2,496,239
Furniture, equipment and leasehold improvements, net	298,268	451,280
Other	33,407	33,407
	$ 2,179,130	$ 2,980,926
Liabilities and Stockholders Deficit		
Current liabilities:		
Accounts payable	$ 852,016	$ 225,999
Accrued wages, salaries and related expenses	213,037	167,905
Unearned licensing revenue	988,426	1,666,667
Unearned research revenue	1,028,752	520,425
Advance for Alzheimer s project	270,140	264,672
Total current liabilities	3,352,371	2,845,668
Unearned licensing revenue, net of current portion	247,107	726,852
Stockholders deficit:		
Series B convertible preferred stock, $0.001 par value; $0.6667 per share liquidation preference; shares authorized: 3,200,000; shares issued and outstanding: 37,500; common shares issuable upon conversion: 3,679	21,703	21,703
Common stock, $0.001 par value; shares authorized: 30,000,000; shares issued and outstanding: 17,153,659 (2003) and 16,849,383 (2002)	17,153	16,848
Additional paid-in capital	42,629,899	42,284,085
Accumulated deficit	(44,089,103)	(42,914,230)
Total stockholders deficit	(1,420,348)	(591,594)
	$ 2,179,130	$ 2,980,926

See accompanying notes.

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Cortex Pharmaceuticals, Inc.

STATEMENTS OF OPERATIONS

	Years ended June 30,		
	2003	**2002**	**2001**
Revenues:			
Research and license revenue	$ 4,765,048	$ 5,777,217	$ 4,263,986
Grant revenue	466,902	655,286	178,849
Total revenues	5,231,950	6,432,503	4,442,835
Operating expenses:			
Research and development	3,801,301	5,042,849	4,409,708
General and administrative	2,620,033	2,444,433	2,431,321
Total operating expenses	6,421,334	7,487,282	6,841,029
Loss from operations	(1,189,384)	(1,054,779)	(2,398,194)
Interest income, net	14,511	72,143	254,855
Loss before cumulative effect of change in accounting principle	(1,174,873)	(982,636)	(2,143,339)
Cumulative effect of change in accounting principle			(530,000)
Net loss before preferred stock dividends	(1,174,873)	(982,636)	(2,673,339)
Dividends on 9% cumulative convertible preferred stock		675	(10,462)
Net loss applicable to common stock	$ (1,174,873)	$ (983,311)	$ (2,662,877)
Basic and diluted net loss per share:			
Loss before cumulative effect of change in accounting principle	$ (0.07)	$ (0.06)	$ (0.13)
Cumulative effect of change in accounting principle			(0.03)
Net loss per share, basic and diluted	$ (0.07)	$ (0.06)	$ (0.16)
Shares used in basic and diluted calculation	16,868,310	16,712,115	16,602,846

See accompanying notes.

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Cortex Pharmaceuticals, Inc.

STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)

	9% cumulative convertible preferred stock	Series B convertible preferred stock	Common stock	Additional paid-in capital	Deferred compensation	Accumulated deficit	Total
Balance, June 30, 2000	$ 27,500	$ 21,703	$ 16,575	$ 41,637,793	$ (92,000)	$ (39,258,255)	$ 2,353,316
Issuance of 52,047 shares of common stock upon exercise of stock options			52	26,203			26,255
Conversion of 12,500 shares of 9% preferred stock into 1,666 shares of common stock	(12,500)		2	12,498			
Adjustment of accrued dividends for conversion of 9% preferred stock				12,375			12,375
Issuance and vesting of stock options for consultants				111,832	92,000		203,832
Non-cash compensation charges for stock options re-priced in 1998				199,757			199,757
9% preferred stock dividends				(1,913)			(1,913)
Net loss and comprehensive loss						(2,673,339)	(2,673,339)
Balance, June 30, 2001	15,000	21,703	16,629	41,998,545		(41,931,594)	120,283
Issuance of 217,500 shares of common stock upon exercise of stock options			217	90,449			90,666
Conversion of 15,000 shares of 9% preferred stock into 1,999 shares of common stock	(15,000)		2	14,998			
Issuance and vesting of stock options for consultants				139,542			139,542
Non-cash compensation charges for stock options re-priced in 1998				41,226			41,226
9% preferred stock dividends				(675)			(675)
Net loss and comprehensive loss						(982,636)	(982,636)
Balance, June 30, 2002		21,703	16,848	42,284,085		(42,914,230)	(591,594)
Issuance of 304,276 shares of common stock upon exercise of stock options			305	128,467			128,772
Issuance and vesting of stock options for consultants				103,167			103,167
Issuance of warrants to purchase 116,000 shares of common stock for services				62,280			62,280
Compensation expense relating to extension of stock options previously granted to former President and Chief Executive				51,900			51,900

Officer						
Net loss and comprehensive loss					(1,174,873)	(1,174,873)
Balance, June 30, 2003	$	$ 21,703	$ 17,153	$ 42,629,899	$ (44,089,103)	$ (1,420,348)

See accompanying notes.

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Cortex Pharmaceuticals, Inc.

STATEMENTS OF CASH FLOWS

	Years ended June 30,		
	2003	**2002**	**2001**
Cash flows from operating activities:			
Net loss before preferred stock dividends	$ (1,174,873)	$ (982,636)	$ (2,673,339)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:			
Depreciation and amortization	155,846	153,176	149,478
Stock option compensation expense	155,067	180,768	403,589
Warrants issued for services	62,280		
Changes in operating assets/liabilities:			
Restricted cash	97,475	11,414	55,000
Accounts receivable	(312,979)	(115,472)	
Other current assets	140,333	(90,193)	(156,877)
Accounts payable and accrued expenses	671,149	(144,556)	(20,891)
Unearned revenue	(649,659)	(1,709,691)	4,321,550
Changes in other assets and other liabilities	5,468	6,562	10,810
Net cash (used in) provided by operating activities	(849,893)	(2,690,628)	2,089,320
Cash flows from investing activities:			
Purchase of fixed assets	(2,834)	(107,870)	(247,494)
Net cash used in investing activities	(2,834)	(107,870)	(247,494)
Cash flows from financing activities:			
Proceeds from issuance of common stock	128,772	90,666	26,254
Payment of 9% preferred stock dividends		(675)	(15,525)
Net cash provided by financing activities	128,772	89,991	10,729
(Decrease) increase in cash and cash equivalents	(723,955)	(2,708,507)	1,852,555
Cash and cash equivalents, beginning of year	1,849,009	4,557,516	2,704,961
Cash and cash equivalents, end of year	$ 1,125,054	$ 1,849,009	$ 4,557,516
Supplemental schedule of non-cash investing and financing activities:			
Conversion of preferred stock to common stock	$	$ 15,000	$ 12,500

See accompanying notes.

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Cortex Pharmaceuticals, Inc.

NOTES TO FINANCIAL STATEMENTS

Note 1 Business and Summary of Significant Accounting Policies

Business Cortex Pharmaceuticals, Inc. (the Company) was formed to engage in the discovery, development and commercialization of innovative pharmaceuticals for the treatment of neurological and psychiatric disorders. Since its formation in 1987, the Company has been engaged in research and early clinical development activities.

In January 1999, the Company entered into a research collaboration and exclusive worldwide license agreement with NV Organon (Organon), a subsidiary of Akzo Nobel (Note 5). The agreement will enable Organon to develop and commercialize the Company s AMPAKINE® technology for the treatment of schizophrenia and depression. In October 2000, the Company entered into a research collaboration and exclusive license agreement with Les Laboratoires Servier (Servier). The agreement, as amended in October 2002, will enable Servier to develop and commercialize the Company s AMPAKINE technology for the treatment of anxiety disorders and memory impairment associated with aging and neurodegenerative diseases, such as Alzheimer s disease (Note 4).

Basis of Presentation From inception through June 30, 2003, the Company has generated only modest operating revenues, the majority of which it derived from its agreements with Servier and Organon, as further described in Notes 4 and 5, respectively. These agreements contributed 91%, 89% and 92% of total revenues for the years ended June 30, 2003, 2002 and 2001, respectively.

Under the agreement with Servier, during the years ended June 30, 2003, 2002 and 2001 the Company recorded research and licensing revenues of $4,756,000, $3,720,000 and $2,087,000, respectively. During the same periods, the Company incurred direct and indirect expenses for the Servier research collaboration totaling $2,098,000, $2,053,000 and $1,148,000, respectively.

Under the agreement with Organon, the Company recorded research and licensing revenues of $0, $2,000,000 and $1,999,000 for the years ended June 30, 2003, 2002 and 2001, respectively. During the same periods the Company incurred direct and indirect expenses for the Organon research collaboration totaling $0, $0 and $1,469,000, respectively.

With the proceeds from the Company s private placement of its common stock in August 2003, Cortex anticipates that it has sufficient capital and committed funding to maintain its operations into fiscal year 2005; however, successful completion of the Company s development program and its transition, ultimately, to attaining profitable operations is dependent upon obtaining additional financing adequate to fulfill its research and development activities, and achieving a level of revenue adequate to support the Company s cost structure. There can be no assurance that the Company will be successful in these areas. To supplement its existing resources, the Company likely will need to raise additional capital through the sale of debt or equity. There can be no assurance that such capital will be available on favorable terms, or at all; if additional funds are raised by issuing equity securities, dilution to existing stockholders is likely to result.

The Company is seeking collaborative or other arrangements with additional pharmaceutical companies, under which such companies would provide capital to the Company in exchange for exclusive or non-exclusive license or other rights to certain of the technologies and products that the Company is developing. Competition for corporate partnering arrangements with major pharmaceutical companies is intense, with a large number of biopharmaceutical companies attempting to arrive at such arrangements. Accordingly, although the Company is presently engaged in discussions with a number of candidate companies, there can be no assurance that an agreement will arise from these discussions in a timely manner, or at all, or that any agreement that may arise from these discussions will successfully reduce the Company s short-term or long-term funding requirements.

Cash Equivalents The Company considers all highly liquid short-term investments with maturities of less than three months when acquired to be cash equivalents.

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Concentrations of Credit Risk Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company limits its exposure to credit loss by investing its cash with high credit quality financial institutions.

Furniture, Equipment and Leasehold Improvements Furniture, equipment and leasehold improvements are recorded at cost and depreciated on a straight-line basis over the lesser of their estimated useful lives, ranging from five to ten years, or the life of the lease, as appropriate.

Long-Lived Assets The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. The Company has not recognized any impairment losses through June 30, 2003.

Revenue Recognition The Company recognizes revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the fees earned can be readily determined; and (iv) collectibility of the fees is reasonably assured.

The Company recognizes research revenue from its collaborations with Servier (Note 4) and Organon (Note 5) as services are performed under the agreements. These agreements include compensation to the Company based upon an annual rate for each full-time equivalent employee that dedicates research to the project. The agreements provide scheduled quarterly payments to the Company in advance of the period during which the services are to be performed. The Company records the resultant revenue from the agreements as it performs the contracted research services.

The Company records grant revenues as the expenses related to the grant projects are incurred. All amounts received under collaborative research agreements or research grants are nonrefundable, regardless of the success of the underlying research.

Revenues from milestone payments are recognized when earned, as evidenced by written acknowledgement from the collaborator, provided that (i) the milestone event is substantive and its achievement was not reasonably assured at the inception of the agreement, and (ii) the Company s performance obligations, if any, after the milestone achievement will continue to be funded by the collaborator at a comparable level to that before the milestone was achieved. If both of these criteria are not met, the milestone payment would be recognized over the remaining minimum period of the Company s performance obligations under the arrangement.

If a collaborator develops and markets a product that utilizes the Company s technology, the Company will be eligible to receive royalties based on net sales of the product, as defined by the relative agreement. The Company will recognize such royalties, if any, at the time that the royalties become payable to the Company from the collaborator.

In November 2002, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board reached consensus on Issue 00-21. EITF Issue 00-21 addresses the accounting for arrangements that may involve the delivery or performance of multiple products, services and/or rights to use assets. Specifically, Issue 00-21 requires the recognition of revenue from milestone payments over the remaining minimum period of performance obligations under such multiple element arrangements. As required, we will apply the principles of Issue 00-21 to multiple element research and licensing agreements that we may enter into after July 1, 2003.

In accordance with the Securities and Exchange Commission s Staff Accounting Bulletin No. 101, Revenue Recognition (SAB 101), as described more fully below, amounts received for upfront technology license fees under multiple-element arrangements are deferred and recognized on a straight-line basis over the period of committed services or performance, which approximates the level of efforts provided, if such arrangements require the Company s on-going services or performance.

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Cumulative Effect of Change in Accounting Principle In December 1999, the Securities and Exchange Commission (SEC) issued SAB 101, which addresses various revenue recognition issues, and specifically addresses revenue recognition for up-front, nonrefundable fees received in connection with research collaboration arrangements. It is the SEC s position that revenues from such fees generally should be recorded over the term of the related agreements.

As required, Cortex adopted SAB 101 in the fourth quarter of its fiscal year ending June 30, 2001. The Company s previous accounting policy was to recognize such nonrefundable fees as revenues when it received the related payments. SAB 101 required Cortex to change its accounting method for the up-front fee from the collaboration with Organon signed in 1999 (Note 5).

After adopting SAB 101, for the fiscal year ending June 30, 2001, the Company restated revenues to include $530,000 of revenues originally recorded when it received the up-front payment from Organon. For the same period, the Company recorded an offsetting cumulative effect of the change in accounting principal of $530,000. There was no net impact on the reported net loss or net loss per share.

Prior year results have not been restated in the accompanying statement of operations. Had this change in accounting principle been applied retroactively, the net income (loss) applicable to common shares and earnings (loss) per share amounts for the fiscal year ended June 30, 2001 would have been as follows:

Pro forma net (loss) income applicable to common shares	$ (2,132,877)
Pro forma basic (loss) earnings per share	($0.13)
Pro forma diluted (loss) earnings per share	($0.13)

Before adopting SAB 101, Cortex applied the related principles to its accounting for the up-front fee from the agreement with Servier (Note 4). Cortex was recording the revenues from Servier s $5,000,000 nonrefundable fee ratably over the three-year research phase of the agreement, which began in December 2000. After amending the agreement in October 2002, Cortex began amortizing the remaining unearned licensing revenues over the two-year period of the amendment s extended research support.

Employee Stock Options and Stock-Based Compensation In December 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure (SFAS 148), which is effective for fiscal years ending after December 15, 2002. SFAS 148 provides alternative methods of transition to the fair value method of accounting for stock-based employee compensation under Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123). SFAS 148 also requires disclosure of the effects of stock-based employee compensation on reported net income or loss and earnings or loss per share in annual and interim financial statements.

As permitted under SFAS 123, the Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), in accounting for its employee stock options, given that the alternative fair value accounting provided for under SFAS 123 requires use of option valuation models that were not developed for use in valuing employee stock options. According to APB 25, no compensation expense is recognized since the exercise price of the Company s stock options generally equals the market price of the underlying stock on the date of grant. Adoption of SFAS 123 for options issued to employees would require recognition of employee compensation expense based on the computed fair value of the options on the date of grant. In accordance with SFAS 123 and EITF Issue 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services, stock options and warrants issued to consultants and other non-employees as compensation for services to be provided to the Company are accounted for based upon the fair value of the services provided or the estimated fair market value of the option or warrant, whichever can be more clearly determined. The Company recognizes this expense over the period the services are provided.

Pro forma information regarding net loss and net loss per share is required by SFAS 123, and has been determined as if the Company had accounted for its employee stock plans under the fair value method. The fair value was estimated at the date of grant using the Black-Scholes option pricing model and the following

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assumptions for the years ended June 30, 2003, 2002 and 2001, respectively: weighted average risk-free interest rates of 2.7%, 3.4% and 4.8%; dividend yields of 0%; volatility factors of the expected market price of the Company s common stock of 99%, 68% and 108%; and a weighted average life of 4.1 years, 4.5 years and 3.9 years.

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Because the Company s employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective assumptions can materially affect the fair value estimate, in management s opinion the existing models do not provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized as expense over the vesting period of the options, resulting in the following pro forma information for the years ended June 30, 2003, 2002 and 2001:

	Year ended June 30,		
	2003	2002	2001
Net loss applicable to common stockholders, as reported	$ (1,174,873)	$ (983,311)	$ (2,662,877)
Stock-based employee compensation expense included in reported net loss		41,226	199,757
Total stock-based employee compensation expense determined under fair value based method for all options	(537,314)	(617,889)	(642,020)
Pro forma net loss applicable to common stockholders	$ (1,712,187)	$ (1,559,974)	$ (3,105,140)
Basic and diluted net loss per share available to common stockholders, as reported	$ (0.07)	$ (0.06)	$ (0.16)
Basic and diluted net loss per share available to common stockholders, pro forma	$ (0.10)	$ (0.09)	$ (0.19)

The pro forma effect on net loss shown above is not necessarily indicative of potential pro forma effects on results for future years. The estimated weighted average fair value of options granted during the years ended June 30, 2003, 2002 and 2001 was $0.54, $1.36 and $1.68, respectively.

In March 2000, the Financial Accounting Standards Board issued FASB Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation, an interpretation of APB 25 (FIN 44 of the Interpretation). As required, the Company adopted the Interpretation on July 1, 2000. The Interpretation requires that stock options that have been modified to reduce the exercise price be accounted for as variable. Prior to release of FIN 44, in December 1998 the Company re-priced previously issued stock options to purchase approximately 970,000 shares of common stock to a price of $0.375 per share, which represented the fair market value of the common stock on the date of the re-pricing. By adopting the Interpretation, the Company now applies variable accounting for these options until such options are exercised or forfeited. Of the options re-priced in December 1998, as of June 30, 2003 options to purchase 265,919 remained outstanding. Consequently, if the market price of the Company s stock increases above $2.50 per share, the fair market value of the Company s common stock on the date that it adopted FIN 44, the Company will recognize additional compensation expense that it otherwise would not have incurred. For the fiscal year ended June 30, 2003, applying the Interpretation had no impact on the net loss or the net loss per share. For the fiscal year ended June 30, 2002, the effect of applying the Interpretation was an increase in the net loss of $41,226,

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with no impact on the net loss per share. For the fiscal year ended June 30, 2001, the effect of applying the Interpretation was an increase in the net loss of $199,757, or $0.01 per share.

Research and Development Costs All costs related to research and development activities are treated as expenses in the period incurred.

Comprehensive Income In accordance with Statement of Financial Accounting Standards No. 130, Reporting Comprehensive Income, all components of comprehensive income or loss, including net income or loss, are reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, including foreign currency translation adjustments and unrealized gains and losses on investments, shall be reported net of their related tax effect to arrive at comprehensive income. For the years ended June 30, 2003 and 2002, comprehensive loss for the Company was the same as net loss.

Net Loss per Share In accordance with Statement of Financial Accounting Standards No. 128, Earnings per Share (SFAS 128), net loss per share is computed based on the weighted average number of common shares outstanding and includes dividends accrued on the Company s 9% Cumulative Convertible Preferred Stock. As of June 30, 2003 and 2002, there were no shares of the 9% Cumulative Convertible Preferred Stock outstanding.

The Company has reserved 4.2 million shares of common stock for issuance upon exercise of outstanding stock options and stock purchase warrants, as well as for conversion of the Company s Series B preferred stock, as further described in Note 3. The effect of the potentially issuable shares of common stock was not included in the calculation of diluted loss per share given that the effect would be anti-dilutive.

Use of Estimates The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual amounts may differ from those estimates.

New Accounting Standards In June 2002, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 146, *Accounting for Costs Associated with Exit or Disposal Activities (SFAS 146).* SFAS No. 146 addresses issues regarding the recognition, measurement and reporting of costs associated with exit and disposal activities, including restructuring activities. This statement requires that costs associated with exit or disposal activities be recognized when they are incurred rather than at the date of a commitment to an exit or disposal plan. The Company will adopt this statement in future exit or disposal activities.

Note 2 Detail of Selected Balance Sheet Accounts

Accounts receivable consist of the following:

June 30,

	2003	2002
Receivables from Servier	$ 368,349	$ 95,017
Receivables for grant projects	13,775	15,287
Other receivables	46,327	5,168
	$ 428,451	$ 115,472

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Together with Servier, Cortex is conducting a cross-national Phase II clinical study in patients with mild cognitive impairment (MCI). Servier has agreed to incur the bulk of the related costs for this study. While Cortex pays many of the associated expenses directly, it receives reimbursement for these amounts from Servier.

Other current assets consist of the following:

	June 30,	
	2003	2002
Prepaid license fees	$	$ 116,296
Prepaid sponsored research	12,458	53,911
Prepaid insurance fees	51,058	52,234
Prepaid financing costs	72,344	47,000
Prepaid consulting fees	25,000	7,500
Other	49,679	73,931
	$ 210,539	$ 350,872

Furniture, equipment and leasehold improvements consist of the following:

	June 30,	
	2003	2002
Laboratory equipment	$ 1,400,804	$ 1,400,216
Leasehold improvements	716,724	716,724
Furniture and equipment	175,431	175,431
Computers and software	317,947	315,701
	2,610,906	2,608,072
Accumulated depreciation	(2,312,638)	(2,156,792)
	$ 298,268	$ 451,280

Note 3 Stockholders Equity

Preferred Stock

The Company has authorized a total of 5,000,000 shares of preferred stock, par value $0.001 per share, of which 1,250,000 shares have been designated as 9% Cumulative Convertible Preferred Stock (non-voting, 9% Preferred); 3,200,000 shares have been designated as Series B Convertible Preferred Stock (non-voting, Series B Preferred); 500 shares have been designated as Series D Convertible Preferred Stock (non-voting, Series D Preferred); 35,000 have been designated as Series A Junior Participating Preferred Stock (non-voting, Series A Junior Participating) and 514,500 shares are presently undesignated and may be issued with such rights and powers as the Board of Directors may designate.

Series B Convertible Preferred Stock outstanding as of June 30, 2003 and June 30, 2002 consisted of 37,500 shares of Series B Preferred issued in a May 1991 private placement. Each share of Series B Preferred is convertible into approximately 0.09812 shares of common stock at an effective conversion price of $6.795 per share of common stock, subject to adjustment under certain circumstances. As of June 30, 2003, the remaining shares of Series B Preferred outstanding are convertible into 3,679 shares of common stock. The Company may redeem the Series B Preferred at a price of $0.6667 per share, an amount equal to its liquidation preference, at any time upon 30 days prior notice.

Common Stock and Common Stock Purchase Warrants

In connection with the restructuring of a note payable, in February 1998 the Company issued to the note holder a five-year warrant to purchase 75,000 shares of common stock at an exercise price of $1.55 per share. During the year ended June 30, 2003, this warrant expired unexercised. In connection with the July 1999 restructuring of the same note payable, the Company issued to the note holder five-year warrants to purchase 200,000 shares

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of common stock at a weighted-average exercise price of $1.48 per share. The exercise prices for these warrants were derived from the fair market value of the Company s common stock on the date of issuance. The Company fully repaid the principal and accrued interest on the note during the fiscal year ended June 30, 2000.

In connection with the engagement of a consultant for capital raising purposes, in December 2002 the Company issued a five-year warrant to purchase 200,000 shares of common stock at an exercise price of $0.67 per share. This warrant becomes exercisable upon the performance of certain services not yet provided, and thus, no expense has been recorded for this warrant to date. In connection with the engagement of a consultant for investor relations purposes, from February 2003 through June 2003 the Company issued five-year warrants to purchase up to an aggregate of 116,000 shares of common stock at a weighted-average exercise price of $0.88 per share. These warrants are fully exercisable and resulted in expense of approximately $62,000 for the fiscal year ended June 30, 2003. The exercise prices for the above warrants were derived from the fair market value of the Company s common stock on the date of issuance.

As of June 30, 2003, the Company had reserved an aggregate of 3,679 shares for issuance upon conversion of the Series B Preferred Stock; 516,000 shares for issuance upon exercise of warrants; 3,657,724 shares for issuance upon exercise of outstanding stock options; and 2,599,866 shares for issuance upon exercise of stock options available for future grant.

Stock Option and Stock Purchase Plans

1996 Stock Incentive Plan The 1996 Plan provides for the granting of options and rights to purchase up to an aggregate of 7,135,214 shares of the Company s authorized but unissued common stock (subject to adjustment under certain circumstances, such as stock splits, recapitalizations and reorganizations) to qualified employees, officers, directors, consultants and other service providers. The exercise price of nonqualified stock options and the purchase price of stock offered under the 1996 Plan, which terminates October 25, 2006, must be at least 85% of the fair market value of the common stock on the date of grant. The exercise price of incentive stock options must be at least equal to the fair market value of the common stock on the date of grant.

Subject to any restrictions under federal or state securities laws, each non-officer employee is eligible to receive incentive stock options, beginning three months following the date of hire. An option to purchase that number of shares equal to 2.5% of the then current annual salary of the non-officer employee is awarded three months from the date of hire. A subsequent option to purchase that number of shares equal to 2.5% of then-current annual salary of the non-officer employee is awarded on the date six months from the date of hire. Additionally, all non-officer employees are eligible to receive a stock option for that number of shares equal to 100% of any salary increase, as of the date of approval of the increase. These options have a maximum ten-year term and vest annually over a three-year period from the dates of grant.

Each non-employee director (other than those who serve on the Board of Directors to oversee an investment in the Company) is automatically granted options to purchase 30,000 shares of common stock upon commencement of service as a director and additional options to purchase 25,000 shares of common stock on the date of each Annual Meeting of Stockholders. Stock option issuances to non-employee directors who serve on the Board of Directors to oversee an investment in the Company are determined separately. The nonqualified options to non-employee directors have an exercise price equal to 100% of the fair market value of the common stock on the date of grant, have a ten-year term and vest in equal increments of 33% on the anniversary dates of the dates of grant.

As of June 30, 2003, options to purchase an aggregate of 2,414,072 shares of common stock were exercisable under the Company s stock option plans. During the years ended June 30, 2003 and 2002, the Company did not issue options to purchase shares of common stock with exercise prices below the fair market value of the common stock on the dates of grant.

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Stock option transactions under the Company s stock option plan for each of the three years in the period ended June 30, 2003 are summarized below:

	Number of shares	Weighted average exercise price per share
Outstanding as of June 30, 2000	1,854,479	$ 0.95
Granted	641,949	2.39
Exercised	(52,047)	2.23
Expired	(2,000)	4.50
Forfeited	(11,775)	3.54
Outstanding as of June 30, 2001	2,430,606	$ 1.32
Granted	455,157	2.48
Exercised	(217,500)	0.42
Forfeited	(39,848)	2.78
Outstanding as of June 30, 2002	2,628,415	$ 1.58
Granted	1,563,195	0.78
Exercised	(304,276)	0.42
Expired	(3,000)	0.38
Forfeited	(226,610)	2.20
Outstanding as of June 30, 2003	3,657,724	$ 1.29
Available for future grant	2,599,866	

Information regarding stock options outstanding at June 30, 2003 is as follows:

	Options Outstanding			Options Exercisable	
Range of exercise prices	Number outstanding at June 30, 2003	Weighted average remaining contractual life	Weighted average exercise price	Number exercisable at June 30, 2003	Weighted average exercise price
$0.38 - 0.75	1,526,710	7.2 years	$0.63	951,710	$0.56
0.76 - 2.06	1,124,979	8.2 years	0.94	814,619	0.97
2.09 - 4.44	1,006,035	7.8 years	2.69	647,743	2.78
	3,657,724			2,414,072	

Stockholder Rights Plan

On February 5, 2002, the Company s Board of Directors approved the adoption of a Stockholder Rights Plan to protect stockholder interests against takeover strategies that may not provide maximum stockholder value. A dividend of one Right for each outstanding share of the Company s common stock was distributed to stockholders of record on February 15, 2002. Each share of common stock presently outstanding and issued since February 15, 2002 also includes one Right. Each share of common stock that may be issued after the date hereof but prior to the Distribution Date (as defined below) will also include one Right. The Rights automatically attach to outstanding shares of common stock detailed above and no separate certificates are issued. The Rights trade only together with the Company s common stock.

Each Right allows its holder to purchase one one-thousandth of a share (a Unit) of Series A Junior Participating Preferred Stock at a purchase price of $75.00 per Unit. The Rights are not currently exercisable, but will become exercisable on the 10th business day following the occurrence of certain events relating to a person or group (Acquiring Person) acquiring or attempting to acquire fifteen percent (15%) or more of the outstanding shares of the Company s common stock (the Distribution Date). If the Rights become exercisable, then any Rights held by the Acquiring Person are void. In such event, each other holder of a Right

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that has not been exercised will have the right upon exercise to purchase shares of the Company s common stock (or common stock of the Acquiring Person in certain situations) having a value equal to two times the exercise price of the Right. Unless redeemed or exchanged earlier by the Company, the Rights expire on February 15, 2012.

The Company has 35,000 shares of Series A Junior Participating Preferred Stock authorized (35,000,000 Units), of which no shares or Units are issued or outstanding at June 30, 2003. Each Unit would entitle the holder to (A) one vote, voting together with the shares of common stock; (B) in the event that the Company s assets are liquidated, a payment of $1.00 or an amount equal to the payment to be distributed per share of common stock, whichever is greater; and (C) in the event of any merger, consolidation or other transaction in which shares of common stock are exchanged, a payment in the amount equal to the payment received per share of common stock. The number of Rights per share of common stock, and the purchase price, are subject to adjustment in the event of each and any stock split, stock dividend or similar event.

Note 4 Research and License Agreement with Les Laboratoires Servier

In October 2000, the Company entered into a research collaboration and exclusive license agreement with Les Laboratoires Servier. The agreement will enable Servier to develop and commercialize Cortex s proprietary AMPAKINE technology for the treatment of declines in cognitive performance associated with aging and neurodegenerative diseases. The indications covered include, but are not limited to, Alzheimer s disease, mild cognitive impairment, sexual dysfunction, multiple sclerosis and Amyotrophic Lateral Sclerosis. The territory covered by the exclusive license excludes North America, allowing Cortex to retain commercialization rights in its domestic market. The territory covered by the agreement also excludes South America (except Argentina, Brazil and Venezuela), Australia and New Zealand.

In connection with the agreement, Servier paid Cortex a nonrefundable, up-front payment of $5,000,000. The upfront payment is being amortized as revenue over the research support period, as extended by the amendment entered into in October 2002. The October 2000 agreement includes research support of approximately $2,000,000 per year for three years, subject to Cortex providing agreed-upon levels of research. The amount of support is subject to annual adjustment based upon the increase in the U.S. Department of Labor s Consumer Price Index. Under the October 2000 agreement, Cortex currently receives annual support of approximately $2,115,000. The agreement also includes milestone payments based upon clinical development and royalty payments on sales in licensed territories.

In October 2002, Servier agreed to provide Cortex with $4,000,000 of additional research support, in exchange for rights to the Company s AMPAKINE compounds for the potential treatment of anxiety disorders, in Servier s licensed territories. The $4,000,000 will be paid in quarterly installments of $500,000 over a two-year period, beginning in October 2002.

Note 5 Research and License Agreement with NV Organon

In January 1999, the Company entered into a research collaboration and exclusive worldwide license agreement with NV Organon, a pharmaceutical business unit of Akzo Nobel of the Netherlands. The agreement will enable Organon to develop and commercialize the Company s proprietary AMPAKINE technology for the treatment of schizophrenia and depression.

In connection with the Organon agreement, the Company received an up-front payment of $2,000,000. The agreement also included support of approximately $3,000,000 per year for the period from January 1999 through January 2001, during which time the Company provided research services to Organon.

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During the fiscal year ended June 30, 2000, the Company received its first milestone under the agreement, triggered when Organon selected an AMPAKINE compound to pursue in Phase I clinical testing as a potential treatment for schizophrenia. During the fiscal year ended June 30, 2002, Organon notified Cortex of its intent to continue developing the selected compound by entering Phase II clinical testing, triggering a second milestone payment of $2,000,000, which the Company received in September 2001. Cortex remains eligible for additional milestone payments based upon further clinical development of the licensed technology by Organon, and ultimately, royalties on worldwide product sales, if any. Unless terminated earlier, the agreement continues until the expiration of all of Organon s royalty obligations, which continue until the expiration of patents covering the AMPAKINE technology or compounds licensed under the agreement.

Note 6 Advance from the Institute for the Study of Aging

In June 2000, the Company received $247,300 from the Institute for the Study of Aging (the Institute) to fund testing of the Company s AMPAKINE CX516 in patients with mild cognitive impairment (MCI). Patients with MCI represent the earliest clinically-defined group with memory impairment beyond that expected for normal individuals of the same age and education, but such patients do not meet the clinical criteria for Alzheimer s disease. The Institute is a non-profit foundation based in New York City and dedicated to the improvement in quality of life for the elderly.

As the funding from the Institute must be used solely for the planned clinical trials in MCI patients, Cortex has recorded the amounts received as restricted cash in the Company s balance sheet. Provided that Cortex complies with the conditions of the funding agreement, including the restricted use of the amounts received, repayment of the advance shall be forgiven unless Cortex enters one of its AMPAKINE compounds into Phase III clinical trials for Alzheimer s disease. Upon such potential clinical trials, repayment would include the principal amount plus accrued interest computed at a rate equal to one-half of the prime lending rate. In lieu of cash, in the event of repayment the Institute may elect to receive the outstanding principal balance and any accrued interest thereon as shares of Cortex common stock. The conversion price for such form of repayment shall initially equal $4.50 per share, subject to adjustment under certain circumstances. Included in the balance sheet is accrued principle and interest of $270,140 and $264,672 at June 30, 2003 and 2002, respectively.

Note 7 Commitments

The Company leases its offices and research laboratories under an operating lease that expires May 31, 2004. Rent expense under this lease for the years ended June 30, 2003, 2002 and 2001 was approximately $295,000, $279,000 and $240,000, respectively. Commitments under the lease for the year ending June 30, 2004 are approximately $276,000.

As of June 30, 2003, the Company has employment agreements with two of its executive officers, which agreements expire in May 2004 and August 2005. The agreements involve annual salary payments aggregating $430,000 and provide for bonuses under certain circumstances. As of June 30, 2003, the Company was committed to severance payments to its former President and Chief Executive Officer approximating $34,000.

The Company has entered into severance agreements with each of its executive officers. In the event of a termination of employment, under certain circumstances, these severance agreements provide defined benefits to the executive officers, including compensation equal to 12 to 18 months of the executive officer s then current salary.

Additionally, in the event that the Company commercializes a compound developed by or under the supervision of one of its senior scientific employees, the Company may be obligated to pay the employee a royalty based on net sales, as defined and subject to adjustment, of products containing the compound.

As of June 30, 2003, commitments under external research agreements for services to be rendered for the year ending June 30, 2004 approximated $361,000. The commitments under the external research agreements do not extend beyond June 30, 2004. Commitments under scientific consulting agreements for services to be rendered for the year ending June 30, 2004 approximated $112,000. Thereafter, such commitments for consulting agreements approximate $58,000 annually.

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The Company has entered agreements with an academic institution that provide the Company exclusive rights to certain of the technologies that the Company is developing. Under the terms of the agreements, the Company is committed to royalty payments. These payments include minimum annual royalties of $75,000 for the year ending June 30, 2003 and for each year thereafter for the remaining life of the patents covering the subject technologies, with the most recently issued patent expiring in December 2018. The agreements commit the Company to spend a minimum of $750,000 per year to advance the AMPAKINE compounds during the three years ending in May 2006. Thereafter, the Company s spending requirements will decrease to $250,000 per year and will continue at that level until the Company begins marketing an AMPAKINE compound. The agreements also commit the Company to pay up to an additional $875,000 upon achievement of certain clinical testing and regulatory approval milestones, and to remit a portion of certain remuneration received in connection with sublicensing agreements. As of June 30, 2003, the Company is committed to pay the academic institution approximately $267,000 related to such remuneration during the year ended June 30, 2004.

Note 8 Related Party Transactions

During the years ended June 30, 2003, 2002 and 2001, the Company paid scientific and other consulting fees to stockholders aggregating $53,000, $70,500 and $96,750, respectively. Under certain circumstances, the Company is obligated to make royalty payments to certain of its scientific consultants, some of whom are stockholders, and to one employee, upon successful commercialization of certain of its products by the Company or its licensees.

Note 9 Income Taxes

The Company uses the liability method of accounting for income taxes as set forth in Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes (SFAS 109). Under the liability method, deferred taxes are determined based on differences between the financial statement and tax bases of assets and liabilities using enacted tax rates. As of June 30, 2003, the Company had federal and California tax net operating loss carryforwards of approximately $38,100,000 and $16,000,000, respectively. The difference between the federal and California tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for California franchise tax purposes and the fifty percent limitation on California loss carryforwards. The federal net operating loss carryforward will begin to expire in 2004 and the California net operating loss carryforward will begin to expire in 2005. The Company also has federal and California research and development tax credit carryforwards totaling approximately $1,200,000 and $495,000, respectively. The federal research and development tax credit carryforwards will begin to expire in 2004.

Utilization of the net operating loss and tax credit carryforwards from the tax years ended on or before June 30, 1992 is subject to an annual limitation of approximately $1,500,000, due to ownership change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. If there should be future changes of ownership, these annual limitations for utilization of net operating loss and tax credit carryforwards may become more restrictive. Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company s net operating loss carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within any three-year period since the last ownership change.

Significant components of the Company s deferred tax assets as of June 30, 2003 and June 30, 2002 are shown below. A valuation allowance of $17,734,000 as of June 30, 2003 has been established against the Company s deferred tax assets as realization of such assets is uncertain.

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Deferred tax assets consist of the following:

	June 30,	
	2003	2002
Net operating loss carryforwards	$ 14,272,000	$ 13,175,000
Capital loss carryforwards		22,000
Research and development credits	1,505,000	1,470,000
Capitalized research and development costs	690,000	1,267,000
Unearned revenue	922,000	1,187,000
Depreciation	105,000	118,000
Other, net	240,000	88,000
Net deferred tax assets	17,734,000	17,327,000
Valuation allowance for deferred tax assets	(17,734,000)	(17,327,000)
Total deferred tax assets	$	$

Note 10 Quarterly Financial Information (Unaudited)

Summarized quarterly financial data for the years ended June 30, 2003 and 2002, respectively is as follows:

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2003 Quarters				
Total revenues	$ 1,122,443	$ 1,381,099	$ 1,378,984	$ 1,349,424
Total costs and expenses	1,804,484	1,660,664	1,520,846	1,435,340
Loss from operations	(682,041)	(279,565)	(141,862)	(85,916)
Net loss	$ (674,405)	$ (275,727)	$ (139,598)	$ (85,143)
Basic and diluted loss per share	$ (0.04)	$ (0.02)	$ (0.01)	$ (0.01)

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
2002 Quarters				
Total revenues	$ 3,069,376	$ 1,102,898	$ 1,153,618	$ 1,106,611
Total costs and expenses	1,907,963	2,077,001	2,003,362	1,498,956
Income (loss) from operations	1,161,413	(974,103)	(849,744)	(392,345)
Net income (loss)	$ 1,195,907	$ (956,406)	$ (839,488)	$ (382,649)
Basic and diluted income (loss)per share	$ 0.07	$ (0.06)	$ (0.05)	$ (0.02)

Note 11 Subsequent Event: Private Placement of Common Stock and Warrants

In August 2003, the Company completed a private placement of its securities with a select group of institutional investors with gross proceeds of $5,000,000. In connection with the transaction, Cortex issued 3,333,334 shares of its common stock at a price of $1.50 per share and five-year warrants to purchase up to 3,333,334 additional shares of its common stock at a price of $2.55 per share. In connection with the private placement, the Company is required to prepare and file with the Securities and Exchange Commission a registration statement for the purpose of registering under the Securities Act of 1933 all of the shares of the Company s common stock that were sold to the investors, as well as the shares of common stock issuable upon exercise of the warrants.

If the price per share of the Company s common stock exceeds $6 per share for 13 consecutive trading days, the Company may call for the issued warrants, subject to certain circumstances. This call provision cannot be implemented by the Company prior to the second anniversary of the date that the registration statement referenced above is first declared effective by the Securities and Exchange Commission.

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Cortex Pharmaceuticals, Inc.

Form 10-K/A

Exhibit Index

Exhibit Number	Description
3.1	Restated Certificate of Incorporation dated April 11, 1989, as amended by Certificate of Amendment of June 27, 1989, by Certificate of Designation filed April 29, 1991, by Certificate of Correction filed May 1, 1991, by Certificate of Amendment of Certificate of Designation filed June 13, 1991, by Certificate of Amendment of Certificate of Incorporation filed November 12, 1992, by Certificate of Amendment of Restated Certificate of Incorporation filed January 11, 1995, by Certificate of Designation filed December 8, 1995, by Certificate of Designation filed October 15, 1996, by Certificate of Designation filed June 4, 1997, by Certificate of Amendment of Restated Certificate of Incorporation filed December 21, 1998, and by Certificate of Designation filed February 11, 2002, incorporated by reference to Exhibit 3.1 of the Amendment No. 1 to Registration Statement on Form 8-A, No. 001-16467, filed February 15, 2002.
3.2	By-Laws of the Company, as adopted March 4, 1987, and amended on October 8, 1996, incorporated by reference to Exhibit 3.2 to the Company s Annual Report on Form 10-KSB filed October 15, 1996.
3.3	Certificate of Amendment of Restated Certificate of Incorporation filed December 15, 2003, incorporated by reference to the same numbered Exhibit to the Company s Quarterly report on Form 10-Q as filed on February 12, 2004.
4.1	Rights Agreement, dated as of February 8, 2002, between the Company and American Stock Transfer & Trust Company, which includes as Exhibit A thereto a form of Certificate of Designation for the Series A Junior Participating Preferred Stock, as Exhibit B thereto the Form of Rights Certificate and as Exhibit C thereto a Summary of Terms of Stockholder Rights Plan, incorporated by reference to Exhibit 4.2 to the Company s Amendment No. 1 to Registration Statement on Form 8-A, No. 001-16467, filed February 15, 2002.
10.2	Consulting Agreement, dated October 30, 1987, between the Company and Carl W. Cotman, Ph.D. *
10.3	Consulting Agreement, dated as October 30, 1987, between the Company and Gary S. Lynch, Ph.D. *
10.31	License Agreement dated June 25, 1993, as amended May 28, 2003, between the Company and the Regents of the University of California, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-Q filed February 12, 2004. (Portions of this Exhibit are omitted and were filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934).
10.44	Lease Agreement, dated January 31, 1994, for the Company s facilities in Irvine, California, incorporated by reference to Exhibit 10.44 of the Company s Quarterly Report on Form 10-QSB filed May 16, 1994.
10.49	Settlement Agreement between the Company and Alkermes, Inc., dated October 5, 1995, incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-KSB filed October 13, 1995. (Portions of this Exhibit are omitted and were filed separately with the Secretary of the Commission pursuant to the Company s Application requesting confidential treatment under Rule 406 of the Securities Act of 1933).
10.60	Amended and Restated 1996 Stock Incentive Plan, incorporated by reference to the same numbered exhibit to the Company s quarterly report on Form 10-Q, as filed on November 14, 2002.

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Exhibit Number	Description
10.64	Research and Collaboration and License Agreement between the Company and N.V. Organon, dated January 13, 1999, incorporated by reference to Exhibit 10.64 of the Company s quarterly report on Form 10-QSB as filed on February 16, 1999. (Portions of this Exhibit were omitted and filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 24-b2 of the Securities Exchange Act of 1934.)
10.65	Amendment No. 1 to the Lease Agreement for the Company s facilities in Irvine, California, dated February 1, 1999, incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-KSB filed September 28, 1999.
10.67	Collaborative Research, Joint Clinical Research and Licensing Agreements with Les Laboratoires Servier dated October 13, 2000, incorporated by reference to the same numbered Exhibit to the Company s Quarterly Report on Form 10-QSB filed November 14, 2000. (Portions of this Exhibit were omitted and filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Ruled 24b-2 of the Securities Act of 1934).
10.69	Employment agreement dated May 17, 2000, between the Company and James H. Coleman, incorporated by reference to the same numbered Exhibit to the Company s Report on Form 10-QSB filed February 12, 2001.
10.70	Severance agreement dated October 26, 2000, between the Company and Maria S. Messinger, incorporated by reference to the same numbered Exhibit to the Company s Quarterly Report on Form 10-QSB filed February 12, 2001.
10.71	Employment agreement dated June 5, 1995 between the Company and Gary A. Rogers, Ph.D., incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-K filed October 15, 2002.
10.73	Amendment dated October 3, 2002 to the Collaboration Research Agreement with Les Laboratoires Servier dated October 13, 2000, incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-K filed October 15, 2002.
10.74	Employment agreement dated October 29, 2002 between the Company and Roger G. Stoll, Ph.D., incorporated by reference to the same numbered exhibit to the Company s Quarterly Report on Form 10-Q, as filed on November 14, 2002.
10.75	Securities Purchase Agreement dated August 21, 2003, by and among Cortex Pharmaceuticals, Inc. and the investors named therein, including the Registration Rights Agreement attached as Exhibit A thereto and a form of Common Stock Purchase Warrant attached as Exhibit C thereto, incorporated by reference to the same numbered exhibit to the Company s Report on Form 8-K filed August 22, 2003.
10.76	Amendment dated August 8, 2003 to the employment agreement between the Company and Roger G. Stoll, Ph.D. **
10.77	Amendment dated December 16, 2003 to the Collaboration Research Agreement with Les Laboratoires Servier dated October 13, 2000, incorporated by reference to the same numbered Exhibit to the Company s quarterly report on Form 10-Q as filed February 12, 2004. (Portions of this Exhibit are omitted and were filed separately with the Secretary of the Commission pursuant to the Company s application requesting confidential treatment under Rule 24b-2 of the Securities Act of 1934).
21	Subsidiaries of the Registrant, incorporated by reference to the same numbered Exhibit to the Company s Annual Report on Form 10-KSB filed October 13, 2000.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
24	Power of Attorney. **
31.1	Certification by Chief Executive Officer Pursuant to Rule 13a-14(a)/15d-14(a), As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Chief Financial Officer Pursuant to Rule 13a-14(a)/15d-14(a), As Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32	Certification Pursuant to 18U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. **

* Incorporated by reference to the same numbered exhibit of the Company s Registration Statement on Form S-1, No. 33-28284, effective on July 18, 1989.

** Incorporated by reference to the same numbered exhibit to the Company s Annual Report on Form 10-K for the period ended June 30, 2003 filed with the Commission on September 19, 2003.