

CORTEX PHARMACEUTICALS INC/DE/
Form DEFA14A
November 10, 2003

SCHEDULE 14A INFORMATION

**Proxy Statement Pursuant to Section 14(a) of the
Securities Exchange Act of 1934
(Amendment No. __)**

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CORTEX PHARMACEUTICALS, INC.

(Name of Registrant as Specified In Its Charter)

N/A

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To Our Shareholders and Friends:

Over the past year, our senior management team and I have been working diligently to set a new course for Cortex Pharmaceuticals. If any of you saw the recent ABC World News Tonight with Peter Jennings or read the Business Week article titled "I Can't Remember", you may have shared my excitement in seeing our small, but innovative company singled out for its breakthroughs in a broad range of neurological and psychiatric diseases.

At this time last year, after I assumed the offices and responsibilities of the President and CEO, I worked with the management of Cortex to define three objectives that would help steer our company toward success. First, we needed to solve the financial problems that we faced; second, we had to develop a financially viable business plan and sell it to the financial community; and third it was critical that we improve our focus on public and investor relation activities.

MAJOR ACCOMPLISHMENTS

During the past twelve months since the last shareholder meeting, Cortex achieved a number of significant objectives:

1. Raised \$9 million dollars to improve a weak financial position
2. Developed a viable business plan that the financial community supports
3. Improved investor relations substantially and increased the visibility of the company to a broader financial community
4. Improved the share price four to five fold and the daily trading volume of the common stock by a factor of 10
5. Increased the market capitalization for Cortex from \$12 million to \$70 million

I would like to elaborate on these successful activities and invite you to read this letter that traces our progress over the past twelve months. I also hope that I can convey the excitement we have about our next steps for Cortex and our plans to make the goal of becoming a leading neuroscience pharmaceutical company a reality.

OUR BUSINESS STRATEGY

We are now ready to initiate the second phase of our strategy to make Cortex a major player within the CNS pharmaceutical market segment. This new phase should span the next three to four years and includes a two-pronged approach to developing value for Cortex and our shareholders' internal business development and external licensing.

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Over the past year, we controlled our expenditures, spending under six million dollars overall. Our entire senior management team took a 20% pay cut for over one-half of the year, and I relinquished my full salary for several months until we were able to obtain additional financial support through the private placement we completed in August. This says something about how tight our finances were, and about our personnel and their belief in our AMPAKINE® technology. The \$5 million private placement included some high quality healthcare institutional investors. The funds raised will allow us to develop some of the very outstanding compounds that we have

in preclinical development, but previously had been unable to push into clinical trials.

The first drug candidate that is undergoing toxicological evaluations is CX717. We plan to file an IND for evaluating this compound clinically during the second quarter of calendar 2004. While it costs millions of dollars to move a compound through clinical trials and eventual submission to the FDA, we only have sufficient funds to start this process at this time.

Our business plan envisions developing some of our products for Orphan drug indications, which indications are defined as having less than 200,000 patients in the United States. Several factors caused us to focus on pursuing these indications. First, the cost of developing a compound for an Orphan drug indication is somewhat less than a standard indication because the Phase III clinical development requirements are reduced, saving us both time and money. Second, we can have a small, focused sales effort if such a product is approved, which again would require less funds than building a large marketing and sales group within Cortex. Finally, while the markets for fragile X, autism, and narcolepsy are not billions of dollars in size, they do nonetheless provide a substantial target for a small startup like Cortex, and are in the neighborhood of \$250-\$350 million of potential annual revenue for each indication. The faster speed to market also conserves patent life, providing us with a longer payback period. One only has to look at how successful Genzyme (GENZ) has been to see the type of business and market value that can be obtained by following an Orphan drug regulatory approach. That company has built a \$1.5 billion business with a market cap of \$10 billion by pursuing Orphan drug indications.

But even these more modest development plans would require Cortex to obtain approximately \$30 million to \$40 million over the next three to four years. We have to find a way to obtain such funding in order to secure the value of our patents and to provide Cortex with a path toward financial success and increased value to our shareholders. In summary, Cortex plans to develop selective AMPAKINE compounds for narcolepsy, fragile X, and a series of day time sleepiness indications that are caused by numerous etiologies. We plan to out-license the remaining larger indications to other pharmaceutical companies because the financial requirements to develop and market such products are well beyond the means of a small biotech startup.

SOUND CAPITAL STRUCTURE

A significant point that we need to emphasize with each and every shareholder of Cortex is that without the capability to fund the clinical development of our compounds, there is no way to create more value for you. Simply looking at share dilution will destroy this company. The existing license agreements do not support any development programs for Cortex. The agreements have some milestones that may or may not be met by the licensees. Obviously, there is also the potential of a royalty stream, but that is unlikely for at least 5 years when some products may reach the market. We are a very long way from obtaining sufficient funds from our existing licensees to adequately support a development program. Waiting for them to succeed before we move forward will cause us to lose years of patent life and value.

An early stage pharmaceutical company needs to generate positive clinical trial results in order to drive its market value in a positive direction. While good publicity is critical, it must be based

on factual data to create value over the long haul. Cortex needs adequate funds in order to pursue such results and we have had a long history of being under-funded. That is why we are asking you to support the proposed increase in authorized shares.

Before I joined Cortex, I was impressed with some of the early proof of principle studies with CX516 that indicated the AMPAKINE compounds can work in humans. After I evaluated the data, it became clear that the doses required, the frequency of dosing, and possibly the cost of goods associated with CX516 relegate it to a compound that can be a proof of principle, but not a viable therapeutic agent. It is a major accomplishment for a company to prove that its technology works in humans, and that has thankfully been accomplished. However, virtually every large pharmaceutical company we have spoken with during the past six months only looks at CX516 for its activity in human clinical trials, none has any interest in the molecule. While we continue to evaluate the potential of CX516 in some selective i.v. uses in the critical care setting, even such uses would require new clinical trials. Obviously, this was a difficult issue to communicate to the market and our loyal shareholders, but it is critical that we move forward and get this issue behind us. We need to hook the fortunes of our company and our technology to compounds that can lead us toward success. Having the knowledge that the technology works in humans is a strong base from which to drive the business forward.

We are an event driven business. With the additional common shares, we have the flexibility to pursue additional financing to develop compounds such as CX717 and to pursue clinical results that potentially may enhance shareholder value. Without such support, we may not be able to adequately develop what I believe is extremely promising technology. All shareholders would suffer from inaction at this point.

Our past technology out-licenses were secured under the duress of inadequate funding, which forced us to accept deals without sufficient funds to develop our compounds. The licenses were critical for the survival of the company, but we have paid a price in time lost getting to the market and in trading away license rights with huge potential for relatively little gain to Cortex. While someday we may get a nice revenue stream from the royalty associated with these agreements, as your CEO I do not want Cortex to ever be in the same position as when I joined this company in 2003. I ask for your support of the increase in share authorization because it is the vehicle that will allow us to optimize our opportunities to create value. Sufficient capitalization will help us obtain the right value for our intellectual property and multiply our chances for success by (a) taking control of our destiny by developing selected compounds for Orphan drug indications as an internal program, and (b) moving other compounds from preclinical development into early clinical trials and thereby creating far superior value for potential license agreements with large pharmaceutical companies. These approaches would allow us to negotiate from a position of strength with potential licensees and optimize the value of the technology for Cortex and our shareholders.

CLINICAL DEVELOPMENT UPDATE

The following discussions focus primarily on CX516, because that is the only compound currently in the clinic for Cortex. We now have AMPAKINE compounds in Phase II studies in five important indications that may provide excellent proof of principle data, and most importantly

one new compound being developed for clinical testing in early 2004. Our licensees have two other compounds in development, Org 24448, which Organon is advancing in trials for schizophrenia, and S18986, which Servier is developing for mild cognitive impairment and Alzheimer's disease. But we can only report on those studies under our control and must wait for our licensees to report their findings in the studies that they have underway.

Enhanced Performance After Sleep Deprivation

Sleep deprivation causes both mental and physical exhaustion. Day time sleepiness is a problem for people with narcolepsy, sleep apnea, shift work and jet lag. In October, we reported on a sleep deprivation study with CX516. Preliminary findings in that study suggest that CX516, compared to placebo, improves performance in a dose-related response. The study involved 10 young healthy men deprived of sleep for 31 hours before they received the drug or placebo dose. Similar studies have already been completed in primates with promising results. Further work is ongoing and we anticipate that complete results will be reported by Dr. Mark George at the American College of Neuropharmacology (ACNP) meeting in December 2003. We expect that considerably more work in this area will be carried out with CX717 next year when we get it into clinical trials.

Mild Cognitive Impairment (MCI)

A total of 175 patients completed enrollment into the MCI trial by the end of June 2003. Results from the data currently under analysis should be available sometime by year end 2003 or early 2004. Under terms of the agreement with Servier, they are paying virtually all the costs associated with this cross-national trial. Cortex will face a difficult decision with CX516, the compound used in this study, no matter what the results of this trial show. Current issues with the low potency and short half-life of this drug dictate that it would not be a viable compound to move forward into Phase III clinical trials. While we hope to show proof of principle of an effect on MCI, the dosage regimen may dictate that the cost of goods required for therapy also may be beyond what any average patient could afford.

Schizophrenia

In October 2001, Cortex received notice of a three-year award, as extended, of up to \$770,000 from the National Institutes of Health (NIMH). This award will support a phase II study using CX516 versus placebo in combination with the antipsychotic drugs clozapine and olanzapine in patients with schizophrenia. Dr. Donald Goff at Harvard University is the principal investigator on this study, which was a follow on to the positive pilot study that he completed in 2001. In September 2001, Organon announced that it would continue to develop AMPAKINE Org 24448 by entering a Phase II trial for the treatment of schizophrenia. Both studies are currently underway and we hope to have some results late in calendar year 2004 or early 2005. Organon is evaluating the compound both as a mono therapy and as a combination therapy with other antipsychotic agents.

Fragile X and Autism

A study is underway evaluating the effect of CX516 versus placebo on a group of patients with fragile X syndrome and a few patients with similar symptoms who are autistic. The study is supported by FRAXA Research Foundation and the Mind Institute at UC Davis. The two centers involved are Rush Presbyterian St. Luke's in Chicago and the University of California at

Davis. The target is to enroll at least 100 patients and we anticipate that enrollment should be completed by the end of 2004. We will learn a great deal about how to evaluate a compound in fragile X patients from this study and that may serve as a springboard for some newer analogs in our library of compounds.

Alzheimer's Disease

A study is underway to enroll up to 35 patients in a trial being conducted by Dr. Thomas Chase at the National Institutes of Mental Health (NIMH) and supported by NIMH funds to evaluate CX516 in Alzheimer's disease after treatment for 3 months. This study expands on the preliminary positive results obtained by Dr. Chase in a pilot study conducted in patients over a 28 day testing period.

PRECLINICAL DEVELOPMENT CX717

With our new funds we have been able to scale up CX717 and produce over 12 kilos of drug during the past few months. In CX717, we have a unique AMPAKINE compound that has approximately 50 times the potency in animal models as compared to CX516. Additionally, we think that the half-life of CX717 in humans should prove to be at least 6 to 7 times that of CX516. What this all adds up to is a compound that should be much more effective with once or twice a day dosing, at doses 50 times less than any one of the daily doses required by CX516. CX717 may provide a path toward developing a very profitable drug product.

The chart below compares the potency, toxicity, and metabolic stability of CX717 to CX516:

Compound Property	Magnitude Relative to CX516		
	CX516	CX691	CX717
Behavioral Potency	1	20 - 50	30 - 100
Metabolic Stability	1	2	5
Safety Margin	1	30	50
Human Half-Life	1 hour	6-7 hours	>8 hours

CX717 is only one of the compounds that builds on the information that we have gathered with CX516 in Alzheimer's and other diseases. We are currently aware of four AMPAKINE compounds in clinical development by Cortex, its licensees, and one major competitor, as shown below:

Current Clinical Status:

Cortex CX516

- Ongoing Phase II U.S. and Europe

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Organon ORG24448

- Ongoing Phase II U.S.

Servier S18986

- Entering Phase II France

Lilly LY451395

- Ongoing Phase II U.S.

We believe that we can accelerate the development of some of the newer AMPAKINE agents through a regulatory pathway for uses in Orphan drug disorders, where new therapies are badly needed. The ongoing discussions with some potential out-licensees always involve our second

generation compounds and indicate a keen interest in the AMPAKINE technology. The issues that prevent us from closing such a deal revolve around the fact that most of our drugs are in preclinical development, and lack the kind of clinical information required in order to secure a reasonable value for Cortex. This again reinforces the concept that we need to add more capital to bring some of these compounds through toxicology and into early clinical trials in order to bring some significant value to our shareholders.

OUR PATENT PORTFOLIO

Our patent portfolio includes over 32 patents covering various structural approaches for literally hundreds of compounds for agents that behave as AMPAKINE compounds (composition of matter patents), and 11 patents that protect the mechanism of action by which AMPAKINE compounds elicit a response at the AMPA receptor (method of use patents). During 2003, Cortex received a notice of allowance from the European Patent Office (EPO) for use of AMPA receptor potentiators to treat defects in memory, cognition, and libido. A similar patent previously issued in the U.S., Mexico, Australia and New Zealand. Cortex successfully fought a significant battle to persuade the EPO that this patent should be allowed, while its allowance was being challenged by a very large competitor. This patent should issue in Europe during the middle of November 2003.

SUMMARY

In conclusion, during the past year we developed a new business plan that is making sense to an informed investment community. We finalized an agreement with Servier for an additional \$4 million of funding and completed a \$5 million private placement of our common stock. We hired a new team of professionals, The Investor Relations Group, based in New York to reintroduce our company and its business plan to pre-qualified analysts and fund managers, as well as other members of the financial community around the country.

Both Jim Coleman and I conducted countless face-to-face meetings with financial professionals to detail the new directions for Cortex. We have had numerous other meetings that included other staff members and Cortex's co-founder, Dr. Gary Lynch, supporting us in gaining recognition for our new approach and for the outstanding technology that is the basis of our company. I made presentations at the UBS Warburg 5th Annual Global Life Science Conference and the Rodman and Renshaw Techvest Healthcare Conference, which contributed to renewed interest in Cortex.

As you know, Cortex also was highlighted in the media this year with numerous exclusive stories on radio and television, as well as in magazines and newsletters. Most notably, Cortex was featured in an ABC news segment on World News Tonight with Peter Jennings and also in a related cover story in the September 1, 2003 issue of Business Week titled, "I Can't Remember".

As a whole, our visibility in both the financial and public community has improved greatly. We increased our market capitalization from \$12 million to approximately \$70 million and increased our daily shares traded from 12-15 thousand shares to over 200 thousand shares.

While we have much more to do to bring success to all of our shareholders, our ambitions and plans go well beyond what we have done so far. The accomplishments and sacrifices made by the company during the past twelve months are worth building upon. We know how to improve shareholder value and the past twelve months can attest to that fact. The company's value has increased five-fold in twelve months. Now we ask for your support to help us to continue our work and potentially achieve new clinical milestones for the technology. Please vote for increasing the authorized shares for Cortex and allow the building process to continue.

/s/ ROGER G. STOLL

ROGER G. STOLL, Ph.D.
President, Chairman and Chief Executive Officer

November 10, 2003

Note This report contains forward-looking statements concerning Cortex's research and development activities, clinical trials and business development plans. Actual results may differ materially, depending on a number of risk factors, including the risks that Cortex (the Company) may be unable to obtain additional capital needed to continue its operations; that the agreements with Organon and Servier will not result in any commercial products or that any additional milestone payments will be earned by the Company; that the Company may be unable to arrive at additional corporate partnerships with other pharmaceutical companies on acceptable terms and therefore be required to independently fund clinical development of AMPAKINE compounds through the sale of additional equity securities or otherwise; that the Company's proposed products may at any time be found to be unsafe or ineffective for any or all of their proposed indications; that competitors may challenge or design around the Company's patents or develop competing technologies; and that clinical studies may at any point be suspended or take substantially longer than anticipated to complete. As discussed in the Company's Securities and Exchange Commission filings, the Company's proposed products will require additional research, lengthy and costly clinical testing and regulatory approval. AMPAKINE compounds are investigational drugs and have not been approved for the treatment of any disease.