

CORTEX PHARMACEUTICALS INC/DE/  
Form DEFA14A  
October 29, 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.

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On October 28, 2003, Cortex Pharmaceuticals, Inc. (the Company ) held a conference call to discuss, among other items, the Company s upcoming stockholders meeting. A copy of the press release dated October 23, 2003 announcing the conference call as well as a transcript of such conference call is attached to this Schedule 14a-12.

Press Release

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## **Cortex to Host Conference Call to Discuss Sleep Deprivation Study Results and Upcoming Stockholders Meeting**

### **Call scheduled for Tuesday, October 28, 2003**

**Irvine, CA**, (October 23, 2003) Cortex Pharmaceuticals, Inc. (AMEX: COR) has scheduled a conference call to discuss recently announced results of the AMPAKINE® CX516 sleep deprivation study, the annual meeting of stockholders and upcoming clinical and financial milestones. The call is scheduled for Tuesday, October 28, 2003, at 1:00 P.M. EST.

Participants are asked to call the following numbers 5-10 minutes prior to the starting time:

From the U.S. and Canada: 1-800-838-4403  
International: 1-973-317-5319

An audio replay of this call will be available from 3:00 P.M. EST on October 28, 2003 through 11:59 P.M. EST on December 12, 2003. Please call 1-800-428-6051 (domestic) or 973-709-2089 (international) and use the access number 310301.

For more information, call: Jane Lin or Dian Griesel, Ph.D. at The Investor Relations Group, Inc. Phone: 212-825-3210.

#### **About Cortex Pharmaceuticals:**

Cortex, located in Irvine, California, is a neuroscience company focused on novel drug therapies for neurological and psychiatric disorders. The Company is pioneering a class of proprietary pharmaceuticals called AMPAKINE compounds, which act to increase the strength of signals at connections between brain cells. The loss of these connections is thought to be responsible for memory and behavior problems in Alzheimer's disease. Many psychiatric diseases, including schizophrenia, occur as a result of imbalances in the brain's neurotransmitter system. These imbalances may be improved by using the AMPAKINE technology. Cortex has alliances with N.V. Organon for the treatment of schizophrenia and depression and with Les Laboratoires Servier for the development of AMPAKINE compounds to treat the neurodegenerative effects associated with aging and disease, including Mild Cognitive Impairment, Alzheimer's disease and Anxiety Disorders. (<http://www.cortexpharm.com/>)

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Transcript

**CORTEX PHARMACEUTICALS, INC.**

**Moderator: Roger G. Stoll**

**October 28, 2003**

**1:00 pm EST**

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Operator

Good afternoon, and welcome, ladies and gentlemen, to the Cortex Pharmaceuticals Inc. conference call. At this time I would like to inform you this conference is being recorded, and that all participants are in a listen only mode. At the request of the company, we will open the conference up for questions and answers following the presentation. Ladies and gentlemen, if you wish to access the replay for this call, you may do so by dialing 1-800-428-6051, or 973-709-2089, with an ID number of 310301; or by accessing the company's Website at [www.cortexpharm.com](http://www.cortexpharm.com).

This conference call contains forward-looking statements concerning Cortex's research and development activities. Such activities are subject to a number of risk factors, including the risk that Cortex's proposed products may be unsafe or ineffective for any or all of the proposed indications, and that clinical studies may, at any point, be suspended or take substantially longer than anticipated to complete. In addition, competitors may challenge or design around Cortex's patents, or develop competing technologies. Also, the risk that Cortex may be unable to secure additional capital needed to continue research activities.

As discussed in the company's Securities and Exchange Commission filings, the company's proposed products would require additional research, lengthy and costly clinical testing and regulatory approval. The AMPAKINE® compounds are investigational drugs, and have not yet been shown to have efficacy in the treatment of any disease.

This conference call is not a solicitation of a proxy. Cortex shortly will be filing proxy materials with the Securities and Exchange Commission for its annual meeting of stockholders to vote on the proposed increase in authorized capital discussed in this conference call. Cortex will mail a copy of the final proxy statement to its stockholders prior to the annual meeting. Stockholders are advised to read the proxy statement carefully, and in its entirety, when it becomes available, because it will contain important information about the proposed increase in Cortex's authorized capital, the persons soliciting proxies and their interest in the proposal and related matters. It will also be possible to obtain copies of the proxy statement and any amendments or supplements thereto without charge at the SEC's Website at [www.sec.gov](http://www.sec.gov), as they become available. I will now turn the conference over to Roger Stoll, Chairman, President and CEO. Please go ahead sir.

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Roger Stoll - Cortex Pharmaceuticals CEO

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Good morning everyone. I hope everyone can hear me clearly. I'd like to start this call by giving a brief overview of our company and its activities over the past 12 months. I will try to review the more current information and emphasize that. I'd like to start out by making some comments about what's occurred over the last 12 months. I think it's been an extremely busy time for the company. We faced some significant challenges, and I'm pleased to say that I think we rose to the occasion on most of those challenges, and did an excellent job in getting ourselves stabilized.

The first thing we did was we were able to raise enough money last October to keep the business going, and that was \$4 million that came to us over a two year period from Laboratoires Servier. Then this past August we were able to add an additional \$5 million through a private placement to our treasury, which actually will now allow us to proceed in bringing at least one more new compound forward into clinical trials, a compound that we have great hopes for. Obviously a lot remains to be done with that, but nonetheless it finally gets us into the position where we

can have more than one option potentially being developed for the marketplace, and that's very critical in this pharmaceutical development business.

We also have made significant progress in the clinical front, and I'd like to briefly review the clinical trials, and where they stand at this point. The most recent announcement we made was regarding a trial in 10 normal subjects that occurred at the University of South Carolina Medical Center. It was related to improving performance after sleep deprivation. It was based upon data that was generated in primates previously at Wake Forest University by Dr. Sam Deadwyler and his staff. There it was shown that both CX717 and CX516 were capable of enhancing performance after sleep deprivation in the primates, and in fact, returned the degree of cognitive activities back to the level, and in fact, slightly above the level that was noted for those primates when they had normal sleep and food.

One of the first things that was requested from us, from a military relationship that was funding those primate studies, was to see if we could get the same type of results in human beings. We conducted that test at South Carolina Medical Center, and had announced a week ago that we were successful in showing that we could improve performance after sleep deprivation in a dose related manner. One of the issues we ran into in doing the human trial was that the only compound we could put into man, because it was the only one that had gone through sufficient testing, was CX516. The dose required in that compound was significantly higher than what the people at the medical center were used to seeing for pharmaceuticals. So they initially agreed to only administer doses that were well below those that had been tested in the primates.

Nonetheless, we are pleased to say that certainly at the higher doses that were administered, we started seeing some positive performance results. They were not as significant as the recoveries we had seen in the monkeys, so early on, we had suggested that we need to go to higher doses. Because there was an excellent safety profile, that resulted from not only what we've done previously with 516, but in this particular study I think the investigator and the people at the university, the IRB, agreed that we could go to a higher dose. So there's another dose being tested at 2100mg, a single dose that is being administered to patients against a placebo group. This is being done by Dr. Mark George. Dr. George will present all of the results for all the doses at a meeting in December. In fact I think the meeting is on December 10 in Puerto Rico, it's the ACNP, he's a member of that group, it's a quite prestigious neuro-pharmacology group. They meet once a year, and he's giving the results of the study at that particular meeting. However, he was good enough, and the university was good enough to allow us to at least share the results, which were positive, for 516 in this trial. So we were pleased to do so, and we did that at the Rodman and Renshaw conference in Boston.

To give you other updates, Organon is proceeding at this point to go with Organon 24448, a compound that came out of our collaboration with them and do further studies in the area of schizophrenia. These are Phase II studies. It is initiating a mono-therapy study and is also currently evaluating doing a combination therapy with an existing schizophrenic compound as a combination therapy with an AMPAKINE, with Organon 24448 as well. We expect those studies to progress and certainly we don't expect anything to be done before the end of 2004. So sometime at the end of that point, or in 2005 we may be at the point where they would be ready to proceed into Phase III. But certainly right now they are just initiating those key studies in Phase II.

They also have notified us formally with a letter that they are going to make a positive decision on depression, so there's a milestone payment that is due in the middle of January 2004. They have sent us a formal notice that they plan to exercise that milestone. So that will be quite positive, that should be a \$2 million payment coming to Cortex in the middle of January.

Servier is just at the point where we're working with them on the MCI trial. As you know, the patient enrollment was completed and just this past week they had their first review of the data, not in terms of analysis, but just the patient enrollment, to make sure that all the data that was being put into the analysis was correct. So they went through a review and it's a trial where we're really doing a lot of quality control, to make sure that you have correct data before you try to enter it into an analysis system. The data, I don't think at this point, is frozen yet. But at any rate, we will shortly have a review and I think we should have the data analyzed by the end of this year. We should certainly know how that study progressed sometime by the end of this year, or possibly early next year, depending how the holidays impact the final decision on the analysis.



We also are proceeding with our Fragile X study. As you know, there are two centers, Presbyterian St. Luke's in Chicago, and UC Davis in California; they are both progressing with the study. We have very good enrollment. The target for that study is well over 100 patients, and we're probably no more than 40% along that way. But they're doing an excellent job of enrolling patients, and we're quite hopeful that by the end of next year we would have some result in Fragile X.

Perhaps the most rewarding thing for us here at Cortex, is to see that we have one of our new compounds, CX717, actually now being initiated in toxicology studies, which is still pre-clinical, but it's what's necessary for us to move those compounds ahead into the clinic. We have also done a number of small pilot studies, all of which add up to now being able to initiate the regular toxicology studies in two species. We're studying it in both rats and dogs, and we're hoping that by the end of first quarter 2004 we would have the results from toxicology and then be able to proceed into the clinic, and actually initiate clinical trials on CX717 in the second quarter of next year.

I think those are the key studies. We obviously have studies underway in Alzheimer's that's going on and in schizophrenia, both of which I really don't have anything new to report. Those studies are progressing satisfactorily as far as we know. We're making payments to our patient enrollment, but it's far too early to say anything about how they are progressing. I think that is the review of the clinical update, the business update. Obviously we're extremely happy that we've been able to not only improve the progress with our compounds at Cortex, but that the market has recognized what we've been able to do. So over the past year both our market cap has gone up from about \$10-\$15 million to the \$70 million range, and the shares traded daily have gone from about the 10-15,000 shares to approximately 200,000 shares on average. That has helped the liquidity. Obviously there's a lot more to do, we recognize that as a company. We need to do a lot more with this company in order to make it the kind of success that I think everyone is counting on. We're all very positive; we see a lot of good things happening. But basically we're heading in the direction of continuing to build, successfully, a business.

We have a couple of other issues. You know that in April we made an announcement that the European patent community had decided to allow a key method of use patent that was related to AMPAKINE compounds and how they contributed to cognition and memory, and libido. That patent issued in the United States, but now was allowed in Europe. We've just gotten notice that by mid November it should issue in Europe. So that's another important milestone, because we had significant competitive activity in that field, so we were very pleased to be able to announce that that will issue at that point.

I also have one other announcement to make, and that is related to an addition to our board of directors. The board has evaluated, and a person has been put forward as an addition to our board of directors. The person is Dr. Peter F. Drake. Dr. Drake has a very, very, good, almost ideal background for this company as a board member. He received his Ph.D. in biochemistry and neurobiology from Bryn Mawr College in 1980. He had worked as a senior research associate in the Department of Developmental Biology & Anatomy at Case Western Reserve.

And then he also, importantly, went on and joined the Wall Street investment firm of Kidder Peabody as a Biotech Analyst in 1983. He continued working in the field of investment banking. And then, I think in around the mid-80s, or late 80s, Dr. Drake co-founded what was called Vector Securities International in Chicago, an investment banking firm that specialized in emerging healthcare companies. That was an extremely successful venture, and Dr. Drake at that point continued to grow that business until Prudential Securities bought that and took it over.

Dr. Drake additionally ended up forming a couple of private funds, two healthcare investment funds, Vector Management Fund, which was a \$230 million Venture Capital Fund, specializing in healthcare technologies; and Deerfield Management, which was a \$2 billion hedge fund that also invested in publicly traded healthcare companies.

Dr. Drake graduated from Bowdoin College. He attended the Wharton School of Business at the University of Pennsylvania. He currently serves on the Board of Directors of Trustmark Insurance Company, a healthcare insurance provider. He is also a member of the board of the Alliance For Aging Research, and a member of the Board of Trustees of Blair Academy. Dr. Drake also served on the Board of Trustees for Bowdoin

College and for Lake Forest Hospital in Illinois, Lake Forest, Illinois.

We're really pleased that we can get this caliber of individual to join our Board. We think it's a significant addition. It will tremendously help us in our dealings in terms of attempting to put together financing and to make sure that we can bring the kind of resources to this company that it needs, in order to bring the technology forward. It offers a lot of hope and promise for patients who require therapy for which there really is not adequate therapy currently. We really think that we have something in terms of being able to add someone to the board who can now give us a bit more direction in the financing area. That's been an area that's been under served, I think, at Cortex for a number of years.

So, as one member of the board, I'm extremely pleased to make this announcement. We will put out a PR statement tomorrow on this, but we thought we'd use the opportunity while investors were calling in, to let them know about this addition to our board.

I think those are the extent of the comments that I'm going to make that we prepared ahead of time. What I really want to do is allow as much opportunity for investors to talk to us and to ask questions about our business and the directions of our business. But I think there's one other important item that I need to spend just one minute on, and that is, you will be receiving a proxy statement for our annual shareholders' meeting, which is to occur on December 9<sup>th</sup>, this year.

In that proxy statement we will be making a request to increase the number of authorized shares on the marketplace. Basically, the common shares would be increased from 30 million to 50 million. I understand that some investors may not like that. But it is an absolutely essential and critical element for this company.

One of the things that I found when I came here last year is that there was a history of significant under funding of this company over the years that it has existed. And the technology has suffered significantly because there hasn't been adequate investment. You cannot get a technology in the pharmaceutical field to market without having a fair amount of money. And millions and millions of dollars are required to do it.

The people who were here, who were my predecessors, did a good job of keeping things going, but there were certainly a lot of compromises that had to be made. Among them, we had to offer licenses sometimes at, I think, values that were less than we would've liked to, because we had to offer them at an earlier stage in order to keep the business going.

We now still have a significant piece of licensing opportunities in front of us. We don't want to squander that. We want to get as much capital value for this company and for our shareholders out of that as we possibly can. The only way to do that is by giving us some options in terms of how we can finance the future development of this technology. If we don't put together a reasonable fund of money in the next two to three years, then I don't think this company would not have a very good future. So, I think it's very critical that we, in the next 12 to 24 months, put together a significant fund that would require us to have somewhere on the order of \$30 million to \$40 million to bring some of this technology to market.

And that money would be applied toward not only fulfilling the business strategy that we've put together for Cortex, which means that in some orphan drug areas, we would bring products to market. But it would also help us bring some compounds into Phase II, where if we did a license for them at that stage of development, we would be able to get a great deal more to fund the future of this company and to get more value out of the technology for the shareholders than we've ever been able to do before.

I think it's critical that we have that option available. We have a lot of people interested in our technology, but every one of them is looking at pre-clinical compounds. Pre-clinical compounds just simply do not garner the value because the risk is so much higher. And every company would like to see some proof of principle for a particular compound in Phase II, before they really are prepared to write a license.

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If you can get that type of work done, you create much more value for shareholders. And that's the point I would like to emphasize is, the only way this company can create value for shareholders is by actually producing clinical results that are meaningful in diseases that are significant. We can't do that without bringing more money on board. We're at the point where the only money that we have is the collaboration with Servier, which basically are funds that are used pretty much exclusively to support Servier and developing compounds for their use.

It does very little to help us move our business along and develop compounds, which might be available for licensing to other companies. We need to put those kind of funds together. We've got a small amount of money that we brought in with that \$5 million placement, which will get CX717 up and into the clinic. And that's an important critical step, but we need to do more. And we need to have the flexibility to be able to achieve those ends.

If we can achieve those ends, we will create value for shareholders. If we are not given those funds, it will probably be a pretty dark day for this company in the future. So, I think it's critical that shareholders evaluate the proposals that we make and make their decisions from the standpoint of the company. The request is going out. We would like to increase the authorized shares. We think it's the right thing for the shareholders, and for the valuation of this company.

So, you will be getting those notices in the mail when the proxy statements are sent out to each of you, and we ask for your consideration at that point.

I will now take questions and answers and I will turn the meeting over to the operator. So operator, if you will please proceed with the question and answer session.

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QUESTION AND ANSWER

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Operator

Thank you, sir. The question and answer session will begin at this time. If you are using a speakerphone, please pick up the handset before pressing any numbers. Should you have a question, please press star-one on your pushbutton telephone. If you wish to withdraw your question, please press star-two. Your question will be taken in the order as received.

Once again ladies and gentlemen, the floor is now open for questions. Should you have a question, please press star-one on your pushbutton telephone. If you wish to withdraw your question, please press star-two.

Our first question comes from Elemer Piros, of Rodman and Renshaw. Please pose your question.

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Elemer Piros - Rodman and Renshaw

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Yes, good afternoon Roger. Thanks very much for the overview. I have two questions. One is, assuming that the MCI tryout is positive, what would be the next steps taken by Servier there?

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Roger Stoll   Cortex Pharmaceuticals   CEO and President

You know, we'd almost have to ask Servier. That's a very difficult question to answer. I have two things that I think I have to put on the table in that regard. Servier has an option that they could proceed with that compound, either as a backup or as a primary compound in MCI and Alzheimer's. In the current discussions that we are having with other pharmaceutical companies, I can tell you there is no one that's particularly interested in 516. They're all very conscious of the short half-life and the high dose and so they are more interested in some of the other compounds that are in our library.

And Gary Rogers has developed a fairly large library of compounds. There are some really outstanding candidates. But they haven't been at the advanced stage of development. So most of the companies that we've talked to, at least, look at 516

as sort of a proof of principle and say that, Look, we can see that AMPAKINE compounds work in humans. That's a very critical step. It's very important to be able to achieve that with a new concept and new therapy, but we need something that has the kind of characteristics from a pharmaceutical dosage form that will allow for adequate compliance for patients that will not be a huge barrier, from a cost of goods standpoint. And it can be successfully marketed. And at that point we have very little interest in 516.

So, from the standpoint of this company, we will not be doing much more with 516 beyond those trials that are now underway. We will be working extremely hard to move 717 along, because it is a compound that does have all the characteristics of potential for once-a-day therapy. It's approximately 50 times as potent in certain indications, at least, as 516. So, it will be a very reasonable dosage. So, the cost of goods per day would be less of an issue.

So, it meets all the requirements of a compound that's important from a pharmaceutical standpoint. And I think most of the companies look at 717 as a very attractive compound. The issue that we have is we don't want to license it out too quickly.

But for 516, there could be an option. There is an area where we still have an unknown. That is, number one, we do not know how much stimulation of BDNF we get at the doses that we're currently administering. And if that BDNF, or Brain Derived Neurotrophic Factor is stimulated significantly, it might mean that there might be the possibility of a maintenance dose that would be a little bit less than what we're giving right now. We have not shown that. It would take a lot to prove that down the road. But that is one of the options that hangs out there.

Additionally, the fragile X indication. I talked with a key investigator there. They realize they're giving a lot of drug. It's an inconvenient dosage, but there is nothing else available. So, the possibility exists that we can develop this in that field if it's successful. But again we don't know the answer to that.

And then finally, the area where there really is some possibility of developing 516 is in the field of an injectable. If you think about some potential injectable uses, which would be short-term critical care uses in a hospital, those are applications for which the dose becomes less limiting. And even the cost of goods might be less of an issue, although it won't entirely be something that we can dismiss. But it could probably be something that we could work out and live with.

So, it's an issue that the development of 516 much beyond where it is now is problematic. And yet there are a couple of areas where, if we have some success in the current clinical trials, we could see that there would be application for that drug. But it won't be in a broad, large field, like MCI or Alzheimer's.

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Elemer Piros - Rodman and Renshaw

Excuse my ignorance Roger, but under the currently existing license agreement with Servier, do they have an access to 717, or not just yet?

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Roger Stoll - Cortex Pharmaceuticals CEO and President

They have not. They've chosen, they actually turned down 717 quite a while ago. That doesn't mean they couldn't come back and express an interest. But currently, 717 is exclusively our compound. We can choose who we want to license it to.

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Elemer Piros - Rodman and Renshaw

That makes sense. And the last question, then would DARPA have sufficient data from the sleep deprivation studies to make a potential funding decision?



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Roger Stoll - Cortex Pharmaceuticals CEO and President

Probably after Dr. George gives his presentation and completes the full analysis of all the data. There was a great deal of data generated during the study and that continues to be generated. He gave us some of the results of some of the key indicators he was looking at. And that is basically all that's been shared with us.

So, I think when the data is completely analyzed and a complete report is written by the clinician at that point, I think that would be submitted to DARPA. And DARPA would probably try to make a decision at that point on how it would like to proceed.

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Elemer Piros - Rodman and Renshaw

So, that would most likely be in the first half of next year?

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Roger Stoll - Cortex Pharmaceuticals CEO and President

The beginning of next year.

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Elemer Piros - Rodman and Renshaw

OK. Thanks very much.

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Roger Stoll - Cortex Pharmaceuticals CEO

Thank you.

Operator

Our next question comes from Dr. Oberlander, a private investor. Please pose your question.

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Dr. Oberlander Private Investor

Thanks for the overview as well, Roger. My question concerns the DARPA sponsored trial, and assuming success, Phase II and Phase III trials. I know it's early to speculate, but assuming success and development of an AMPAKINE in the improvement of cognition after sleep deprivation, particularly from a military standpoint, it seems like these trials in the positive are very short trials. How long do you speculate that a Phase II or a Phase III trial might be?

Roger Stoll - Cortex Pharmaceuticals CEO

Well you know the actual indications that DARPA are looking for, are something that we would just have to show a proof of principle in. Basically what they would like us to do then, would be to develop compounds toward some more classical clinical indication, and being able to get that approved through the Food and Drug Administration. Then I think the application within the military would be almost an off label use, for which they would have generated some data that says it works, and they would have done some clinical trials. But it probably wouldn't be a formal approval of that kind of indication.

But to go back to your question and maybe just looking at it from another side, what would it take to get an early clinical approval like for 717 if we want to push it out the door as quickly as possible? The best that we could do is try to go for an orphan drug indication like narcolepsy or fragile X, and attempt to go down the orphan drug route where the Phase III studies would be significantly less, both in size and number, as compared to standard NDA approval. If you take a drug like Provigil which is out there right now, and you look back at what it took for them to get an approval, they did about a 250 or 300 patient Phase III trial, and they did it against, I think it was daytime sleepiness, and showed that Provigil could overcome those factors in narcoleptics, and that's how they got their approval.

So if you put that all together, and say what would it take for us to finish a Phase I, Phase II and then if everything is successful, and I'm emphasizing the fact that obviously if we had some clinical hiccups we would have to take a little longer, but if everything were successful, in round 3.5 - 4 years you could have a product at the FDA. Assuming you had adequate funding and assuming that all the trials were successful when you ran them in patients. But that's what it would take.

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Dr. Oberlander Private Investor

Excellent. Thank you.

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Operator

Ladies and gentlemen, at this time the floor is still open for questions. Should you have a question, please press star, one, on your touchtone telephone. If you wish to withdraw your question, please press star, two. Our next question comes from Dorin Frai. Please pose your question.

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Dorin Frai Private Investor

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My question revolves around Organon or Servier; if they finish the Phase II and proceed with the Phase III, how would that reflect on Cortex in terms of the timetable and milestone payments?

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Roger Stoll - Cortex Pharmaceuticals CEO

Organon is progressing with Organon 24448 in schizophrenia. It looks like a pretty reasonable compound at this stage, it's very early. So it's a bit hard to say what the exact timing would be. Certainly they need to get good results in their upcoming Phase II trials. If those are completed successfully then they'd probably go into a fairly large set of Phase III, because to get an indication such as schizophrenia, either as a combination or as a mono-

therapy, would take a significant number of patients in Phase III, and I think there's still a significant number of years ahead of them before they would at all be able to file an NDA, or a European filing, for that matter. So I think they've got a long road to go. It is not a short course. I'm almost hesitant because it's another company doing it, it's their work and it's their responsibility to comment on how much time it would take. I think you'd really have to take that up with Organon.

If you wanted a sort of rule of thumb, I would say certainly you could be in the four to five year timeframe. But that depends on a lot of clinical successes and other factors going right, all of which right now are unknowns. That's about the best, I know that's a vague answer, but that's probably the best that I could give you. If you wanted to address it directly, you'd have to ask Organon.

The Servier part of your question, they're just finishing Phase I with 18986, so they'll be going into Phase II this year yet, as far as I understand. But that's a long way from getting a product out. But it certainly would be nice to see them have a success with that compound in Phase II. But I think again, we're at very early stages, we don't know much about 18986, and to really get that answer again, you'd have to talk to Servier. However, I think the thing that's encouraging to us in general is that one, with 516 we've had some successes, at least from a proof of principal. It looks like Organon 24448 certainly is producing cognitive responses in schizophrenic type patients, so again, it's looking good. There are even compounds that Lilly has put out that are looking like they're in Phase II.

So we've got four to five different AMPAKINE compounds that are now in Phase II development throughout the world. That speaks well for the technology overall. I think it's an important thing to keep in mind that this is a very, very new technology, and it's now going into a pretty significant phase of testing, because these are the efficacy trials that are very, very critical to a drug's future. That's happening across a number of companies, and in a number of places in the world. I think it speaks well for the technology that we've brought forward. Obviously between the patent position that we have and the library of compounds that we have, the future really looks good.

I think it's very, very dependent upon us being able to put adequate funding together. It is probably the single most critical thing that has faced this company in the past, and continues to face us. So it's an important aspect for us to be able to find ways to put funding together to really give these compounds a chance to shine. The technology, there's more and more outstanding data coming together. We get periodic updates from Dr. Gary Lynch at the University of California at Irvine, and he does a lot more fundamental research, but there's some really exciting things happening in the ability of these compounds to increase BDNF levels in animal models. That can be an extremely exciting, outstanding opportunity for these compounds, and it's pretty much unexplored yet. So I would say the potential is probably greater than any of us have ever imagined.

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Dorin Frai Private Investor

Mr. Stoll, as a follow up question please, conceivably one could imagine that if some of the partners advance and finish Phase III within maybe even the two to three year timeframe, Cortex might receive royalties from their partners.

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Roger Stoll - Cortex Pharmaceuticals CEO

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No. I would have trouble saying even conceivably we could be in that kind of a timeframe. I do not see us getting royalties from our current partners; I see us getting perhaps some milestone payments, but no royalties. Royalties would require a marketed product. I don't think there'll be anything on the market in less than probably four years or five years. That's sort of the timeframe that's reasonable, and that's assuming things go well. So there isn't a two to three year timeframe. The fastest thing we can do, absolutely, is for us to chase one of the orphan indications, to have success with it, and to have something filed within the next 3.5 to 4 years. If we put adequate funds together that can be done, and that can change the valuation of this company tremendously.

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Dorin Frai Private Investor

I wish you continued success.

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Roger Stoll - Cortex Pharmaceuticals CEO

Thank you very much for your call.

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Operator

Our next question comes from John Hood of First Associates. Please pose your question.

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John Hood First Associates

Good afternoon. I appreciate your stressing; I think it's about 10 times now, the issue of raising capital. You're chuckling, and it's appropriate to do so, but it's also important that people understand precisely where you are at this stage. Having said that, your initial indications are, if I read correctly, you're looking for about \$80 million, assuming the current stock price.

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Roger Stoll - Cortex Pharmaceuticals CEO

No, but go ahead with your question.

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John Hood First Associates

I would also venture to say that if you're looking at three to four years out, then you're probably looking at additional financing as well, or certainly alliances or partnerships with someone else. In your estimate, how much total capital, since you've mentioned, three, four years or longer, do you feel you will need if you are successful with your main products to market?

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Roger Stoll - Cortex Pharmaceuticals CEO

Let me answer that in two parts. Number one, to bring one of these orphan indications to market, I need about \$40 million, about \$10 million a year as a rough number. Actually we've got it in our business plan at about \$9.2 million. That's costed out more precisely, but let's say for round numbers, \$10 million, and that's how I came to the \$40 million. That money can come from several sources. It can come from private placement financing, as we've done in the past, it can also come from licensing deals. If we move 717 along, it is not inconceivable that if we have some early results in Phase II that we could strike a tremendous licensing deal for that money, and bring additional monies in. So the sources that we're pursuing currently, and that we continue to pursue, are; one, trying to put a robust licensing deal together that would value fairly the technology that we have, and that's an important aspect. We do not want to do a cheap deal, because we think that most of the big companies talking to us want fairly board



licensing rights, and in order to give away pretty much everything else that we've got left, we need to bring in enough to give us a chance to bring the product to market. So the cost is in that \$30-\$40 million range.

If we are also going to take some of the other compounds and perhaps move them along into Phase II so that we can strike a good deal and keep 717 ourselves, if that is a path that's possible, then I think we'd need some additional funds just to get them out of toxicology, through Phase I and into a good efficacy trial in Phase II, at which point I think you could strike a very, very good license for a particular compound. To actually optimize the value of the technology that we have, we should really be bringing several compounds along, getting them into Phase II, and licensing each compound out for a very specific indication. We probably won't have the luxury to do that, either from financial wherewithal or from the standpoint of having the kind of freedom to do those kinds of things. I think other things will happen that will prevent us from getting there.

Two, we certainly do have the option of bringing one of these compounds along through an orphan NDA, and that's a \$40 million deal. Then if we want to bring something else along, that would require additional financing. We do have about \$32 million left in milestone payments from Organon and Servier. Obviously if we did another licensing deal with one of the major pharma companies, that would also bring significant amounts of money in. We're not going to do one that we have to do under duress and just throw away our technology, that's just too painful. We really want to optimize what we can get for the technology that's been put together, and for the intellectual property that we have.

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John Hood - First Associates

May I ask you strategically, you're inclined to push toward the orphan drug approach, in view of the fact that it would kind of give you some traction and kick start you. Is that the strategy you are inclined to work toward, or are you more broadly based?

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Roger Stoll - Cortex Pharmaceuticals - CEO

I think it's a critical part of the strategy, in other words, we don't want to be dependent just upon the licensing deals with other companies, because there is one fact, once you've done that deal, as long as they meet the timeframes and the milestones, how things are being done and the overall speed to market and to the point that someone else made earlier saying, "Well when can you get royalties", royalties are a long way off, and it's not going to support this company in the foreseeable future. I would probably say not in the next four to five years. After that time, yes, we could probably have some significant funds in here. But between then and now we really have to move ahead on our own.

There's one other point that I should make on a licensing deal. Some of these companies, when they approach us, and we're talking significant licensing deals, would like to be able to have the option of placing some of their money at our disposal by taking an equity position. Again, the emphasis on increasing the available, the authorized shares in the marketplace is that right now we have no shares left. If you read the proxy when it comes out, you will see that basically there are no shares available to us to do a deal. In fact, in order to do this last \$5 million round, we reached down and took some of the shares that we had gotten approval for to place in the employee stock option program. We took over 800,000 shares out of that program and put it in the financing deal, because we wanted the financing, we wanted to move this company ahead. The employees did the right thing, they have faith in the technology, but that's how short we are. So we need to get increased authorization just to be able to do another licensing deal, because most likely someone would come in and say maybe they'd want five, or six, or seven million shares of Cortex stock as an equity investment to protect their investment as well. Right now we couldn't even write a deal like that with another company. So there are several reasons that we're asking for the increased authorization.

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John Hood First Associates

Great. I appreciate your comments.

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Operator

Ladies and gentlemen, as a reminder, should you have a question, please press star, one, on your pushbutton telephone. If you wish to withdraw your question please press star, two. Our next question comes from Kelly Walsh, a private investor. Please pose your question.

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Kelly Walsh Private Investor

Hi. I'm wondering, do you have any concern that patents will expire before Cortex has the opportunity to capitalize financially on the technology?

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Roger Stoll - Cortex Pharmaceuticals CEO

Let me answer that question this way. If we don't get more funding, it could become an issue. Right now we have, people have done a good job of managing these patents, and so I think a lot of the patents have just issued within the last couple of years. So we have some good patent life still ahead of us. But we can't squander that anymore. I think it's critical that we put enough resources behind this company to really move it in an expeditious manner. We really need to move it much faster than we've been moving in the past. We've sort of been surviving, but we haven't been moving forward at an accelerated pace. We really need to do that much more rigorously. In order to do that, we need to get some financing put together. While I don't think we have squandered a lot, we could be farther ahead than we are now, and have more patent life. I think we still will have pretty substantial patent life, and it's not a barrier in the discussions we're currently having with companies. Most of the patent life is still in front of us. So you could conceive that even in the next four to five years, someone coming to market might still have somewhere around 12 years or 13 years of patent life left when they come to market.

So we haven't lost it yet, but I think we're at a very critical stage, so it's a good question. It's something that companies in our business are always in a race against the clock. When you start your filing for a patent, that's when the clock starts ticking, and you've got to get something out and leave a pretty significant amount of time on that clock in order to get a return on the investment. As I've said, you're spending millions of dollars. This company has put in over \$40 million into this technology so far, and as I've stated, we've got at least that much more to put into it. That's not an unheard of number at all for a company trying to get into this type of business with brand new technology. But it is one that starts putting up barriers. You have to get a good return on your investment, and that means you have to have significant patent life left. So we're at a fairly

critical point.

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Operator

If there are no further questions, I will now turn the conference back to Roger Stoll.

Roger Stoll - Cortex Pharmaceuticals CEO

OK. Well I'd like to thank all the investors who tuned into this presentation. I hope that we've been able to clarify some issues for the company. We're open to your questions at any time, obviously. We look forward to meeting with you at our annual shareholder meeting, where we can give you some more answers to questions if something has been left unsaid at this point. I hope you've gotten some feel for where we are and where we would like to go as a business. All of us here at Cortex thank you for your investment in this company, for your faith in our technology, and we will drive very hard to create value for all of you. Thank you very much.

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Operator

Ladies and gentlemen, if you wish to access the replay for this call, you may do so by dialing 1-800-428-6051 or 973-709-2089 with an ID number of 310301. You may also access the company's Website at [www.cortexpharm.com](http://www.cortexpharm.com). This concludes our conference for today. Thank you all for participating, and have a nice day. All parties may now disconnect.

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