NEOTHERAPEUTICS INC
Form 8-K
August 27, 2002

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934

August 22, 2002
Date of Report (Date of earliest event reported)

NEOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**000-28782**	**93-0979187**
(State or other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

157 Technology Drive Irvine, California	**92618**
(Address of principal executive offices)	**(Zip Code)**

(949) 788-6700
(Registrant s telephone number, including area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Item 9. ***Regulation FD Disclosure***

NeoTherapeutics, Inc. held a conference call on Thursday, August 22, 2002, to discuss and answer questions regarding its recently announced strategic and organizational changes. A replay of the conference call is available on its website at www.neot.com. Included below is an unofficial transcript of the conference call. During the conference call a question regarding Neotrofin clinical trials in Parkinson s disease was asked and Dr. Rajesh Shrotriya, the Company s Chairman of the Board, Chief Executive Officer and President, intended in his response to indicate that given the Company s limited financial resources, it would not be initiating new studies of Neotrofin in patients with Parkinson s disease at this time. NeoTherapeutics, Inc. is furnishing the information contained in this Current Report on Form 8-K pursuant to the Securities and Exchange Commission s Regulation FD.

Transcript:

Operator: Good morning. My name is Mandy and I will be your conference facilitator today. At this time, I would like to welcome everyone to the NeoTherapeutics conference call. All lines have been placed on mute to prevent any background noise. After the speaker s remarks, there will be a question and answer period. If you would like to ask a question during this time, simply press star and the number 1 on your telephone keypad. If you would like to withdraw your question, press the pound key.

Thank you Dr. Shrotriya. You may begin your conference.

Rajesh Shrotriya: Thank you, Mandy. Good morning everyone and thank you for joining our conference call this morning, my first as the C.E.O. and Chairman of the Board. With me today is John McManus, our newly appointed Head of Strategic Planning and Finance.

Before I begin, let me remind you that this presentation contains forward-looking statements regarding future events and the future promise of NeoTherapeutics and our subsidiaries that involve risks and uncertainties that could cause actual results to differ materially. These risks are described in further detail in the Company s reports filed with the Securities and Exchange Commission.

Since Friday of last week we have issued a series of press releases that hopefully convey the new direction our Company is headed. We have some major challenges ahead of us, but I know that we also have excellent opportunities and a team of committed, experienced employees in whom I have a great deal of confidence.

On Friday, August 16, the Board of Directors of the Company announced my appointment as Chairman and Chief Executive Officer. I also retain the title of President of the Company. My plan is to move quickly to transform and streamline the Company in order to improve value to shareholders.

Let me walk you through this plan and talk about some of the steps that have already been taken and some that we expect to take over the next several weeks. The plan is to lower the monthly expenses or burn rate, by focusing on preparing Satraplatin, our lead anti-cancer drug, for phase 3 clinical study, and to complete licensing discussions for our anti-psychotic drugs.

Consistent with this focus, and some aggressive cost-containment measures, we expect to reduce the monthly burn rate to below $500,000 by next month. John will have more to say about this later. Lowering monthly expenses and focusing the Company on the activities that have value to investors and to other pharmaceutical companies should improve our ability to access capital. We would like to complete a small interim financing in the next several weeks.

As many of you know, we have a shareholder meeting set for September 5 and the proxies for this meeting have been mailed. Shareholders are being asked to approve a reverse stock split and to allow the Company to issue up to $10 million in equity. Following the reverse stock

split, we plan to change the name of the Company to reflect our new strategic direction. We are also working to arrange a second financing to follow on to the reverse split and name change. It s our goal to refocus the Company s strategy, reorganize its operations, rebuild its finances and change its name as soon as possible. I would urge all shareholders to vote their proxies in favor of this split and authorize to issue equity in order to help us achieve our goals.

While I understand that this is not a popular option, we believe it to be our most prudent option at this time. This will allow us to quickly move forward with our strategy to restore value to our shareholders. If you have already voted your shares and would like to change your vote, please contact John McManus at (949) 788-6700.

Plans are important, but its implementation that makes the difference between success and failure. With that in mind, I have appointed a dedicated experienced management team who are motivated and focused on success. The leaders of my team include Dr. Gino Lenaz, John McManus, Martyn Gunning, David Helton, Dr. Ashok Gore and Michael Volk.

Let me say a few words about these leaders. Dr. Gino Lenaz will oversee the development of the Company s anti-cancer drug portfolio. Dr. Lenaz is an oncologist with a proven track record of developing anti-cancer drugs. He has spent nearly 20 years at Bristol-Myers Squibb in the anti-cancer drug development area, where he played a key role in bringing numerous anti-cancer drugs to the market. Gino was also instrumental in bringing Satraplatin to the Company and he will lead its development.

John McManus will manage finance and the strategic planning area of the Company. John has already played a central role in the development and organization of the Company and has worked literally non-stop since Friday, August 16, beginning within minutes of my appointment. His broad experience in finance, the financial markets and his strategic planning, I believe, will be of great value to the Company.

Martyn Gunning will be responsible for business development, where his first priority will be to pursue alliances aggressively. Martyn s extensive experience in business development and alliances will help us achieve our goals. In fact, I have told Martyn that at this time, his sole responsibility is to bring us an out-licensing agreement or agreements for our anti-psychotic drugs and attention deficit drugs. And I have asked him to spend 100% of his time towards that goal. I have also made all resources, technical and otherwise, available to him.

David Helton, who gained his experience at Eli Lilly and Company, will oversee basic research, pre-clinical activities and will assist Martyn in alliances in the CNS carrier. Dave and his team are responsible for the development of the Company s anti-psychotic drugs and will continue to work on other promising drugs.

Dr. Ashok Gore will oversee compliance, quality assurance and manufacturing. Ashok s over 30 years industry experience in this field will ensure that our trials are performed in a manner consistent with the highest standards that I have established as a goal for the Company.

Michael Volk will manage the accounting and SEC reporting functions. Mike has served as the Controller for the past year and I m confident that his past experience as a C.P.A. and an audit manager at Ernst & Young will ensure that our financials are complete and accurate.

A very small, lean, and I believe more efficient organization today. We have a laser-like focus on accomplishing our strategic plans and objectives that we have very clearly established. We have a lot of work ahead of us and we face a great challenge. However, I do believe and I repeat I do believe we have some valuable technology assets and a very strong team. I m committed to success and will look forward to communicating our progress regularly.

Now I would like to turn the call over to John McManus, who will discuss our financial position, re-organization and financial strategy. John.

John McManus: Thanks, Raj, and good morning everyone. The Company filed its 10-Q with the SEC and released our earnings announcement earlier this week. The net loss for the quarter was $5.1 million, while cash and equivalents at June 30 were $2.7 million. Early in July, the Company raised $1.1 million through the placement of common stock.

Just as we have announced changes to the corporate strategic direction of NeoTherapeutics, we will also be making changes in the finance area. Our challenge in the finance area is simple. We need to reduce monthly expenses and bring new capital to the Company. First, as Raj indicated, we have reorganized the Company to improve efficiency and simplify the corporate structure. Importantly, these efforts will allow us to bring the monthly expense or burn rate to below $500,000. This compares to a monthly burn of over $1 million during the second quarter. This reduction is being accomplished by eliminating all research on Neotrofin, including winding up of the clinical trials.

Significant reductions have also been made in administration. The net result is that the total number of full-time equivalent employees is now 21, a reduction of approximately 23 employees. We plan to achieve this level of expense next month and have already taken steps to get to this level through the staff reductions and other cost-cutting measures. Further, we will be looking at everything the Company does in our effort to beat our target.

Second, we have initiated discussions with a number of parties regarding an interim financing. We would like to complete this financing within several weeks and then we will pursue a larger financing in conjunction with the name change and reverse stock split. We also plan to discuss with NASDAQ the Company s listing status. Our strategic plan is designed to enable the Company to retain its listing status on NASDAQ and we are working with NASDAQ officials to inform them of the specifics.

We are also encouraged by indications from some of our largest shareholders that they will support the Company by voting for the reverse stock split and authorization to issue equity at the September shareholders meeting. I would also like to urge all of you to vote for the approval of the reverse stock split and the issuance of new equity.

We have an aggressive plan in place and are engaged in swift implementation of that plan. In less than one week, we have made some difficult but necessary cuts, which will allow us to continue the development and/or licensing of our key products and improve our ability to attract capital. We plan to also act swiftly in obtaining this capital and are committed to keeping our shareholders and potential investors informed.

Now I ll turn the call back to Raj.

Rajesh Shrotriya: Thanks, John. I hope you can see that we are very serious about turning things around at this Company. Within three working days that I ve had the job, we have made some major changes and we hope to continue to demonstrate rapid progress in implementing our strategic plan. We commit ourselves to working diligently to improve value to shareholders and will communicate our progress regularly.

We would now be happy to answer any questions that you may have.

Operator: At this time I would like to remind everyone, in order to ask a question please press star then the number 1 on your telephone keypad. We ll pause for just a moment to compile the Q&A roster.

Your first question comes from Alex Blanton with Ingalls & Snyder.

Alex Blanton: Hi, Raj.

Rajesh Shrotriya: Hi, Alex.

Alex Blanton: Can you tell me when that reverse split would become effective? When do you think?

Rajesh Shrotriya: I ll have John answer that question.

John McManus: Well, Alex, you know, the shareholder meeting is scheduled for September 5th, so first we have to get to the 5th and get the approval to implement the reverse split. Once we get that then it will take some time. I can t tell you exactly how long at this point; once we have the approval we can act on it, but it would take some time to implement. I can get back to you with the specifics once I get a clearer indication from our attorneys.

Alex Blanton: I mean is it a matter of a couple of weeks, or what are we talking? I m not trying to pin you down, but

John McManus: No, it s very fast. I mean it s much it s shorter than that.

Alex Blanton: Okay.

John McManus: Once we have the approval, we can act very, very quickly.

Alex Blanton: So something like mid-September. And how many shares are outstanding now?

John McManus: The actual number of shares outstanding at the end of June was 33,682,224. And then we raised $1.1 million in July at I believe it was $0.17 a share. So that s basically what we ve got outstanding at this point. It s approximately 39 million shares.

Alex Blanton: So okay around 40,000. What s the reason for choosing 25? I mean that s going to reduce your outstanding shares to something like 1.6 million.

John McManus: I m going to I wasn t actually here when the decision was made to choose 25, but my and maybe Raj can add something to this, but I think at the time that the decision was made, the stock price was around $0.08 - $0.09 cents a share.

Alex Blanton: Yup.

John McManus: And I think they wanted to make sure that the reverse split accomplished two things. One, that it I mean the bottom line is that there s around 40 million shares outstanding.

Alex Blanton: Yup.

John McManus: And there s approximately 10 million shares worth of stock options and warrants that are that have been issued.

Alex Blanton: Yup.

John McManus: Many of those options and warrants are way out of the money, but nonetheless you have to have authorized shares to cover those. And so

Alex Blanton: Right.

John McManus: the Company found itself in a position where it essentially didn t have any more shares that it could issue. So the reverse you have two options, you can either do a reverse split or you can ask shareholders to approve an increase in the authorization. The second objective was to try to get the stock price back above a dollar to satisfy one of the NASDAQ s requirements for continued listing on the Exchange.

Alex Blanton: Right.

John McManus: So the 25 to 1 ratio was chosen at that time to accomplish both of those objectives.

Alex Blanton: Is that firm or is I don t know how the proposal is. Where did you doing 25 or doing up to 25? In other words is there

John McManus: Yeah, that s the situation

Alex Blanton: Is there any way to change that? The Board

John McManus: The Board can take a look at that ratio, you re right. Yeah.

Alex Blanton: So you can do less than that.

John McManus: Yeah, I believe that s correct.

Alex Blanton: Okay. Also I m not clear on the status of all of your studies and what s going to be licensed out, what s going to be stopped at the moment and so on. For example, Parkinson s, spinal cord, chemo side effects you sort of lump them all together in statements that have been made, but could you give us some more detail on that?

Rajesh Shrotriya: Yes, I d be pleased to talk about that, Alex. The most exciting platform that we have is our anti-psychotic drugs. Anti-psychotic drugs this is a multi-billion dollar market. We believe we have some very good compounds, about eight of them. And we don t have resources and plans to take those compounds into clinic ourselves. And we are hoping, as a top priority, to out-license those drugs.

Alex Blanton: Have you done any studies on those?

Rajesh Shrotriya: We have done the pre-clinical profiling on those drugs and receptor binding and some toxicology limited toxicology.

Alex Blanton: Is that Neotrofin?

Rajesh Shrotriya: No.

Alex Blanton: No.

Rajesh Shrotriya: These are compounds that just have numbers at this time.

Alex Blanton: Okay.

Rajesh Shrotriya: We call them anti-psychotic platforms.

Alex Blanton: Okay.

Rajesh Shrotriya: In addition, we have a drug called 339 that has shown activity in animal models of Attention Deficit Disorder. And that drug has very exciting profiles.

Alex Blanton: That s not Neotrofin either?

Rajesh Shrotriya: That s not Neotrofin either. So those are our two highest priorities and we think most likely candidates that will be of interest to other pharmaceutical companies.

Alex Blanton: So those will be licensed?

Rajesh Shrotriya: Yes.

Alex Blanton: And what about the Neotrofin studies which, I guess the ones I just mentioned Parkinson s, spinal cord, chemo side effects those studies?

Rajesh Shrotriya: Neotrofin license Neotrofin is also available for licensing, but I m afraid, because of the history of its number of clinical trial failures, the interest in Neotrofin is limited at this time.

Alex Blanton: Okay.

Rajesh Shrotriya: But certainly it is available for those who would be interested in pursuing Neotrofin.

Alex Blanton: So will all those studies be halted as you indicated earlier?

Rajesh Shrotriya: Well, Alex, let me repeat, we are trying to make up the limited resources that we have.

Alex Blanton: Yes.

Rajesh Shrotriya: And few pending that we have left with us we are trying to divert their usage into the most productive use at this time. And I believe that we ll be going after the anti-cancer indications like either neuropathy, or pursuing Satraplatin at this time.

Alex Blanton: Yeah, I understand that. So these other things are then going to be put on the shelf for the moment.

Rajesh Shrotriya: Until we can find either a partner or our financial situations change or we have spare time and spare money.

Alex Blanton: Well that makes a tremendous amount of sense. Thanks. I ll get off.

John McManus: Thanks, Alex.

Operator: Your next question comes from Patrick Powers with Powers Capital.

Patrick Powers: Hi, Raj and John. I ve got two questions. It s still unclear to me are you going to continue to look at Neotrofin as far as the chemo-induced neuropathy is concerned? And the second question is what changes have taken place at the Board level already, if any?

Rajesh Shrotriya: Well, yes. Let me as a chemotherapy-induced trial of Neotrofin is underway. We have some 37 patients entered in that trial. That trial is about to be completed. It was a 50 patient trial. The second question about the Board changes, the only Board changes that have taken place right now are that Mr. Sam Gulko, who was the Board member and our C.F.O, he retired as of Tuesday. And his seat has become available for the Board.

Patrick Powers: Okay.

Rajesh Shrotriya: And that s the only change. And of course the second change is that I m now the Chairman of the Board.

John McManus: Pat, on the question about Neotrofin, the Parkinson s Disease study is completed. The spinal cord injury study is complete in terms of enrolling patients and expense. So there s no more money that s going to be spent on those studies. And we re going to basically let the chemo neuropathy trial complete and, you know, we ll do an analysis of that. But in terms of spending capital and devoting resources, you know, there s nothing of significant nature going in that in those directions. We ll see what the study the neuropathy study shows and if we have some exciting data we probably will take it out and see if we can find somebody that has an interest in it.

Patrick Powers: Okay. I take it the Parkinson s data wasn t exciting?

Rajesh Shrotriya: Well, let me say that this is very preliminary data. This is in very small patients. The efficacy we saw was that two hours point, but not at one-week point. I as a clinician, with my 30 years of drug development in neurology, I wouldn t pay much I would not put my dollars behind that indication.

Patrick Powers: Okay.

John McManus: We have we think we ve got some great potential in Satraplatin and there is a great deal of interest in the anti-psychotic drugs and that s where we re going to devote our resources.

Patrick Powers: Okay.

Rajesh Shrotriya: Thank you, Patrick.

Patrick Powers: Sure. Thank you.

Operator: At this time I would like to remind everyone, in order to ask a question, please press star then the number 1 on your telephone keypad. We ll pause for just a moment to compile the Q&A roster.

Your next question comes from Elemer Piros with Rodman and Renshaw.

Elemer Piros: Hello, Elemer Piros from Rodman and Renshaw. Good morning, Raj. Congratulations on your appointment and John, welcome back. I have a question about Satraplatin. Raj, could you please remind us I believe the compound was in phase 3 clinical trials could you please tell us what were the observations there? And based on those observations, how would you design the phase 3 trial?

Rajesh Shrotriya: That s a very interesting question. Phase 3 trial was conducted in prostate hormone refractory prostate cancer patients. And that trial showed that patients treated with Satraplatin produced survival advantage over competitive arm. Right now we are in discussions with the FDA regarding the design that s most efficient, in order to get registration approval with as few patients as possible and as quickly as possible.

So our hope is I mean, Satraplatin like all platinum compounds cisplatin and carboplatin have had activity in a number of tumor types, non-small cell lung, gastric, colorectal and what have you. So we are now discussing with the FDA as to what is the most judicious way of getting this drug to the market. And we have been in discussion ever since. In July in fact, we were to have a meeting, but the meeting has now been postponed to the second half of September. And we are hoping that at that time, I will be able to discuss with you more clearly as to what, going forward, will be the study design.

Elemer Piros: Okay. Thanks very much for that. And Neotrofin in chemo-induced neuropathy, when do you anticipate data from that trial from the 50 patients?

Rajesh Shrotriya: We had announced that the data will be available by the end of this year and results would be available sometime early next year.

Elemer Piros: Early next year. Okay. Having watched some major announcements from companies that develop quote, unquote targeted cancer therapies, and having they ve suffered a number of major setbacks. I m sure that there is an increased interest in an orally available platinum compound at the moment. Would you consider co-developing the compound with a company that focuses on oncology?

Rajesh Shrotriya: Absolutely.

Elemer Piros: Okay. Thank you very much, and congratulations, again.

Rajesh Shrotriya: Thank you. Thank you very much.

Operator: Your next question comes from Tony Shearer with Merrill Lynch.

Alex Washburn: This is actually Alex Washburn with Summit Capital. How are you doing, Raj?

Rajesh Shrotriya: Hi, Alex.

Alex Washburn: One quick question for you. In the past you ve discussed the possibility of a strategic partnership or sale in the Company. Are you currently working with an investment bank to accomplish this?

Rajesh Shrotriya: Yes indeed. Leerink Swann & Company were hired by the Company several weeks ago and they have been making effort in that direction, yes.

Alex Washburn: Anything you can say to update us on this?

Rajesh Shrotriya: Not really. Not at this time.

Alex Washburn: Okay, thank you.

Rajesh Shrotriya: Thank you.

Operator: Your next question comes from Dan DiPietro with SCO Financial Group.

Dan DiPietro: Good morning. Most of my questions were already answered, but I guess you d mentioned that you re going to be speaking with the FDA on the development path for Satraplatin in mid-September, but do you have any sense of an estimate for how much you think it would require? How much capital it would require to develop Satraplatin to a point in which, you know, it s mature enough, where you felt you could created enough value?

Rajesh Shrotriya: Dan, that s again a very good question. And as you know very well, the cost will depend upon the design of the trial that we agree with the FDA. The most important thing for us is to have FDA buy in into our protocol and strategy. We don t want to start a trial thinking that this is what FDA would approve. And depending upon the design of the trial, the costs can vary significantly. It could be from anywhere from $10 million and up. But I think it all will depend on the number of patients and the duration of the study and what the outcome measures are. Are there survival studies or can we get some quality of life issues or even objective tumor responses? All those decisions are being discussed as we speak.

Dan DiPietro: Okay, thanks. Do you have clinical sites that have expressed interest in getting on board once you ve, you know, set a protocol?

Rajesh Shrotriya: Oh, yes. In fact right now we are telling all those sites and we are ready to move very swiftly once we know what the study design is going to be and once we can secure financing we ll move very swiftly, just as we did with Alzheimer s Disease trial. We did a 541 patient trial in 12 months and from the word go, till the reporting of results from April to April. In 12 months we did that. And we have our plans to do exactly the same thing with Satraplatin.

Dan DiPietro: Okay, great. Thanks a lot.

Rajesh Shrotriya: Thank you.

Operator: At this time I would like to remind everyone in order to ask a question, please press star then the number 1 on your keypad. We ll pause for just a moment to compile the Q&A roster.

Your next question comes from Patrick Powers with Powers Capital.

Patrick Powers: More questions. First of all, I understand there s three seats on the Board that come up for re-election next spring. Do you know which Directors those are?

Rajesh Shrotriya: Yes. One is Eric Nelson.

John McManus: Yeah, Pat Powers, it would be Eric Nelson, Paul Silverman and the third seat was Sam Gulko. So that seat would be open at this point in time.

Patrick Powers: Okay. Second question I didn t catch the name of the investment bank that you were working with. Could you repeat that for me?

John McManus: That s Leerink Swann & Company. They re out of Boston.

Patrick Powers: Okay.

John McManus: Their expertise is health care. They re a very specialized group out of Boston.

Patrick Powers: Okay, good. And then on the genetics side of things, anything happening there at all or has that gone away?

Rajesh Shrotriya: Well we closed the operations as of July.

Patrick Powers: Uh huh.

Rajesh Shrotriya: But we retain the licensing arrangements that we had with Pfizer and we also have rights to the technologies that were discovered during the time that we owned it.

Patrick Powers: Okay. So there s still more licensing possibilities there then?

Rajesh Shrotriya: Yes.

Patrick Powers: Okay. And then, last question Raj, I know some time ago you were talking about the possibility of partnering with companies in India to do, you know, to give them a U.S. presence and to help them through the FDA processes and that type of thing. Is there anything still in the works on that?

Rajesh Shrotriya: Yes indeed. There is one company from India that is very interested in using us as a conduit to come into the United States. And that is still intact. The we don t want to deviate from our focus at this time as to what we have to accomplish, but certainly we can afford from time point of view we will certainly offer our services to any such alliance that makes business sense for us.

Patrick Powers: Okay.

Rajesh Shrotriya: We are very open. And we are keeping those alliances alive.

Patrick Powers: Okay, thank you.

Rajesh Shrotriya: Thank you.

Operator: There are no further questions at this time. Sir, do you have any closing remarks?

Rajesh Shrotriya: Yes indeed. I would like to set a tone for two things. Number one, first of all I will thank you for participation in this conference and secondly, going forward, I would like to have a very transparent and communicative company at NeoTherapeutics. Please feel free to call either me directly or John McManus or any one of us any time you have any questions. Thank you very much.

Operator:	Thank you for participating in today s NeoTherapeutics conference call. This call will be available for replay beginning at 11 o clock am Eastern Time today, through 11:59 pm Eastern Time on August 27, 2002. The conference ID number for the replay is 5349119. This concludes today s conference call. You may now disconnect.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEOTHERAPEUTICS, INC.

By: /s/ RAJESH SHROTRIYA

Rajesh Shrotriya, M.D.
Chairman of the Board, Chief Executive Officer and President

Date: August 27, 2002