SPECTRUM PHARMACEUTICALS INC
Form 8-K
December 19, 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

December 11, 2002
Date of Report (Date of earliest event reported)

SPECTRUM PHARMACEUTICALS, 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 5. Other Events and Required FD Disclosure

NeoTherapeutics, Inc. held a conference call on Wednesday, December 11, 2002, to discuss and answer questions regarding its recently announced name change to Spectrum Pharmaceuticals, Inc., recent financings and strategic plans and objectives going forward. A replay of the conference call is available on its website at www.spectrumpharm.com. Included below is an unofficial transcript of the conference call.

Transcript:

Operator: Good afternoon. My name is Samantha and I will be your conference facilitator today. At this time I would like to welcome everyone to the Spectrum Pharmaceuticals 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 then the number 1 on your telephone keypad. If you would like to withdraw your question, press the pound key. Thank you.

I would now like to turn the call over to Dr. Rajesh Shrotriya, Chief Executive Officer and Chairman of the Board of Spectrum Pharmaceuticals. Thank you Dr. Shrotriya, you may begin your conference.

Rajesh Shrotriya: Good morning everyone and thank you for joining us in today s conference call. With me today are Dr. Luigi Lenaz, President of our Oncology Division, and John McManus, Vice President of Strategic Planning and Finance.

Before I begin, let me remind everyone that this presentation contains forward-looking statements regarding future events and the future performance of the company 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 report filed with the Securities & Exchange Commission.

Today NeoTherapeutics begins as Spectrum Pharmaceuticals. Our new name symbolizes the fact that we are now moving to the next phase in the restoration of your company.

Our first task when the new management team took over in the third week of August of this year was to stop the bleeding, which we accomplished within weeks. Then we moved to stabilize and refocus the company.

Today we believe that the company is back on its feet and now it is time to really begin moving forward. Our strategy going forward is to work expeditiously to bring revenue and profits into the company reducing the need to issue equity.

Our agreement with GPC Biotech for the development of satraplatin ensures the development of this product without worry for constantly raising cash. And it has already generated $2 million in revenue without issuing a single share.

We expect another $2 million milestone in 2003 and look forward to milestone and royalty payments down the road.

Supplementing the revenue potential of the GPC agreement we must use our partnership with JB Chemicals and Pharmaceuticals, a leading pharmaceutical company in India.

Earlier this year we had announced a partnership with JB Chemicals called Neo JB. Given the financial challenges the company faced earlier this year, no progress was made in moving this

venture forward. However, over the past several months, we have been in active discussions with our Indian partners about moving this venture forward much more rapidly.

JB Chemicals and Pharmaceuticals has also been encouraged by the recent progress they have seen in our company and in improvements they have noted in the company s financial position and its strategic focus.

JB Chemicals and Pharmaceuticals is an internationally known pharmaceutical company headquartered in Mumbai India. Its products are marketed in over 50 countries, and it has 12 manufacturing sites producing a diverse range of high quality product drugs for domestic use and as a supplier to international companies.

In addition to their own research and development activities, they manufacture and sell intermediates, specialty pharmaceuticals and high quality genetic drugs.

JB is a high quality, low cost manufacturer which provides Neo JB with a key competitive advantage in addressing the generic markets in the United States. They re also a highly profitable company. Earlier this year they reported a profit growth of 34.65% outperforming the industry in India.

Given JB s manufacturing advantage and desire to market products in the United States and our expertise in managing the US regulatory process, we have focused the venture on the generic market in the United States.

Genetic drug sales were estimated to be $10.8 billion in 2000 and are expected to double to nearly $20 billion by 2005 as the healthcare industry continues to look for ways to reduce cost and many more high volume drugs come off patent.

I emphasize here that our strategy is to take advantage of expertise and infrastructure that s already in place and not to invest significant capital in building new facilities or capabilities.

Our generic strategy and joint venture with JB Chemicals is a low capital, low risk strategy that leverages on existing capabilities in both organizations to address its very large and growing market need. Approvals are also much faster for generic drugs which we hope will expedite our ability to bring in revenue and profits to the company.

Let me repeat once again, we remain an oncology focused specialty pharma company. Our strategy is to use revenue and profit from the joint venture to fund the acquisition of additional oncology drugs, their development and ultimate commercialization.

Let me provide a brief update on the status and plans for our key development products.

At the end of September within less than six weeks of taking over the reins of the company, we signed a co-development agreement with GPC Biotech under which Spectrum Pharmaceuticals may receive up to $22 million in license and milestone payments in addition to royalties and payments under a supply agreement.

GPC Biotech also agreed to pay all development costs, which they have estimated to be approximately $30 million.

On October 1, 2002, we met with the US Food & Drug Administration to discuss the Phase 3 study of satraplatin. The Joint Development Committee of the satraplatin composed of developers and (unintelligable) from GPC Biotech and Spectrum meet at regular intervals.

In consultation with the experts from both sides of the Atlantic and taking into account FDA s comments, the protocol is currently being finalized. Plans and a strategy for site selection, monitoring and data management are now being evaluated and finalized. We expect the enrollment to begin by the middle of the year.

Neoquin or EO9 is in Phase 1, Phase 2 trial in superficial bladder cancer. The first patient, a 39-year-old woman has now completed the study in United Kingdom. She has shown complete response to Neoquin treatment, both clinically and verified by histology examination of the tissue sample.

Encouraged by this finding, we are now in the process of expanding this study, add more clinical sites and investigators which is likely to accelerate patient and recruitment into this study. The second patient has just been enrolled.

Our plan for our elsamitrucin, our third oncology drug in clinical development is to begin a 50 to 60 patient Phase 2 study in refractory non-Hodgkin s lymphoma during the second half of 2003.

Presently, we are working with Bristol-Myers Squibb on the production of drug supplies for this study. We expect to recruit sites, manage and monitor the trial ourselves which will keep costs to a minimum.

For those of you unfamiliar with elsamitrucin, we licensed this drug last year based on our enthusiasm about data in a refractory non-Hodgkins lymphocyte study.

In that Phase 2 Study, 31 patients who had failed at least one other treatment were given elsamitrucin. Twenty-five percent of the patients who received elsamitrucin showed an objective response.

Our personal strategy for neurology remains to out-license drugs discovered in-house. Within the past couple of weeks, we released data presented at the Society for Neuroscience, demonstrating the exciting potential of NEO69, a drug candidate for Attention Deficit Disorder and NEO376 and NEO392, new novel anti-psychotic drugs with unique methods of action.

All these three compounds address large market opportunities and will take significant resources to develop. For that reason, we are seeking to co-development or out-license these compounds.

Now I ll turn the call over to John McManus, our Vice President of Strategic Planning and Finance.

John McManus: Thanks Raj, and welcome everyone. Over the past three months, we have raised approximately $3.2 million and settled approximately $650,000 in vendor payables.

We take dilution seriously and have worked very hard to balance our desire to minimize dilution to current shareholders with our need to raise capital to improve the company s financial position and fund the development of our drug candidates.

The current shares outstanding are approximately $2.4 million.

At the end of the third quarter we had approximately $200,000 in cash and equivalents. During the first half of October, we received a $2 million license payment from GPC Biotech, and we raised $938,000 from five investors during late November.

We have reduced our monthly expenses to approximately $400,000 per month and made major improvements to our balance sheet by paying down and settling old accounts payable.

We believe that we currently have adequate resources to operate through the second quarter of 2003.

Let me address the funding strategy for the key products in our current portfolio. First, the development of our lead drug, Satraplatin will be funded entirely by GPC Biotech, our co-development partner for this drug.

In addition to paying all of the costs for development, GPC Biotech will pay Spectrum Pharmaceuticals $1 million in cash and purchase $1 million in equity at a 50% premium to market upon the dosing of the first patient in a Phase 3 study. We expect this to happen around the middle of next year.

Our second drug, Neoquin, or EO9, is being developed in Europe in cooperation with NDDO Oncology. Generally, the relative costs of clinical trials are cheaper in Europe.

As Raj indicated, we expect to begin a Phase 2 study of elsamitrucin in non-Hodgkin s lymphoma in the second half of next year. The formulation work has been paid for, and we are currently working on a budget for the Phase 2 study.

Since we will manage the study in-house, we expect to benefit from lower costs, and will have more to say about this next year.

We made significant progress in reducing our monthly expenses from about $1.7 million per month during the second quarter of 2002 to our target of about $400,000, $500,000 per month for the fourth quarter.

Looking to 2003, we reiterate our previous guidance of a targeted monthly expense rate of approximately $300,000. Even at this lower level of monthly expense, we expect to move forward with the development of Satraplatin and Neoquin, and be able to implement our generic strategy through our joint venture with JB.

Now I ll turn the call back to Raj.

Rajesh Shrotriya: Thanks John. As you have heard, and I hope you agree, we have accomplished a great deal at Spectrum over the past proverbial 100 days. And we have plans in place to show even more progress over the next 100 days. We have spent as much time planning and looking ahead since August as we have addressing the challenges, our new name marks a turning point for the company as we focus on the opportunities that lie ahead.

We hope that you will look ahead with us and find our future as exciting as we believe it is. Now we will be happy to answer any question that you might 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.

Again, in order to ask a question, please press star, then the number 1 on your telephone keypad.

We re pausing for just a moment to compile the Q&A roster.

Your first question is from Alex Blanton with Ingalls & Snyder

Alex Blanton: Good afternoon. John, how many shares were issued to satisfy these vendor outstanding payables?

John McManus: Alex, there s about approximately 369,000 shares.

Alex Blanton: Three hundred sixty-nine thousand shares. And one of the issues that I see mentioned, by people who are following the company, is there going to be any more of that or is that finished?

John McManus: Well there may be some more. We are talking to some selected people. And let me emphasize selected. We chose the people who we negotiated these settlements with very carefully. One of the five we did the first settlement with is a clinical site that was relatively small.

But the other four are all companies that we re continuing to do business with, that we view as partners going forward. These are people who view us the same way, very much want to see us succeed and participate in that success.

I think there was some I ve heard some questions about, you know, whether people were forced to take stock and they only took it because they didn t have a choice. That s kind of a silly thing. I mean if somebody didn t believe in the company, the last thing they would do would be to move themselves from a creditor to a debtor from a debtor to a shareholder because the shareholder wouldn t get anything if they thought the company was going to go bankrupt.

So these people made these decisions based on their confidence in us going forward. The transactions were negotiated at a price right around the market at the time the agreements were signed. And to the extent that we would do additional settlements, we would do the same kind of thing.

There are restricted shares. And again, they re with people who view us and we view as partners going forward, not as people that are going to be out there doing things that might be harmful to our stock price and to our other shareholders.

Alex Blanton: Restricted, in other words, they can t sell those shares for a period of time?

John McManus: That s correct.

Alex Blanton: And how long of a time is that?

John McManus: Well it depends. We have to file a registration statement. And that would then have to go into effect. It s roughly speaking, 60 to 120 days, you know, 60 being the best case scenario time-wise, and 120 probably being the worst case scenario.

Alex Blanton: They have the right to force you to do that?

John McManus: No.

Alex Blanton: No?

John McManus: No. We ve agreed to file the registration statement. So I think, you know, we would do what we agreed to do. But they can t they have no impact on the timing of how quickly that gets approved and processed by the SEC.

Alex Blanton: Well if you filed a registration statement, would that be an underwritten offering or would they just be selling this?

John McManus: No, it would just give them the right at some future time to their stock if they wish to.

Alex Blanton: But do you believe that most of them will continue to hold it?

John McManus: Well I think they re you know, I can t speak for them with absolute certainty. But, you know, I think they re interested in the future of the company. They may hold some. They may sell some.

I would be reluctant to say what they were going to do even if I was managing an account. But, you know, our hope is that they are going to stay on for the long term because they like

what we are doing and they re going to participate in what we re doing going forward. And they know that if we re successful that their stock is going to be worth a lot more than the price it was issued for.

Alex Blanton: Just a couple more questions on this topic. You have a cash outlay of $400,000 a month at the moment going down to $300,000. Do you see are these is stock issued for past debts, or do you see it as something you ll be issuing in lieu of cash to vendors? Could you explain that please?

John McManus: No in this in the first case, this was principally shares issued for old very old payables.

Alex Blanton: Okay.

John McManus: And going forward, the negotiations that we have had have all been around very old payables.

Alex Blanton: Yes. So this is not part of your ongoing expense?

John McManus: No. We ve been working to try to get the balance sheet in shape. And this is just was just part of that effort.

Alex Blanton: Okay now if some of these people do want to sell their shares, wouldn t it behoove them to notify you in case you were aware of someone who would want to buy some shares because it s now a very thin market. After the split it s a very thin market out there. And anyone who wanted to buy a significant amount would have a hard time doing it.

So do you have in mind some investors who might want to buy a significant amount of shares in case some of these people do want to sell so it doesn t disturb the marketplace?

John McManus: I have not hesitated to point people who have had an interest to that effect to the SEC filing related to the agreement in which the names of the five parties are printed. And, you know, I think that s what we ll continue to do. We don t want to you know, we can t get in the middle of a transaction. That s not something we re allowed to do.

But certainly we would not hesitate and have not hesitated to point people to public documents that have those names in there. And I think your point is a good one. It is a thin market, which works both ways whether you re selling or buying.

Alex Blanton: Okay, thanks a lot John.

John McManus: Thanks Alex Take care.

Operator: Your next question is from Dr. Marholm with MD Management.

Marholm: Yes, thank you. I just had an inquiry about Neotrofin in relation to peripheral neuropathy. I believe that was an ongoing study. And I m just curious as to where we re at with that study or if it would be discontinued. Thank you.

Dr. Rajesh Shrotriya: The trial has been completed. At this time the data is all being compiled. And within a short period of time, we will have something to say about this. But there are no patients being treated at this time.

Marholm: Thank you very much.

Operator: Again, in order to ask a question, please press star then the number 1 on your telephone keypad. Your next question is from Marietta Whittlesey with MedEduca

Marietta Whittlesey: Good afternoon Dr. Shrotriya. I think you ve done a miraculous job in turning the company around so far. My question actually also pertains to the peripheral neuropathy study. But also,

the Neotrofin in Alzheimer s, the Phase 3 results. Are you planning to publish those or make them available to the scientific community in some way?

Rajesh Shrotriya: That s a good question. In fact we have been looking at different strategies because some people remain very interested in Neotrofin. And there are people who are looking at us to why maybe the availability of this drug that some people have have good responses, that lot of patients will vouch for the drug.

Whereas when you pull data on 500 patients, you just can t find the statistical significance the FDA expects. So there are some people who have expressed desire. And our plan is to make all the data available to anybody who is interested.

Marietta Whittlesey: Terrific. Good. Thank you very much.

Rajesh Shrotriya: You re welcome.

Operator: At this time, Dr. Shrotriya, do you have any closing remarks?

Rajesh Shrotriya: Yes, I would just like to thank all those people who have taken the trouble of being on this call. And I would like to thank you for your continued support. We are here totally committed. We have 18 people as we speak.

And each and every employee of the company is totally committed and dedicated to the company and to keep building the value for shareholders. I tell you most of our employees have not only commitment of time, but also of the resources. Many of us have worked without salary or without any gain from the company.

This is a challenge that everybody is facing. And we are absolutely confident that we will be successful.

John McManus: Raj, I wanted to add one other thing. The other thing we have in addition to changing the name, we have launched a new Web site today. The address for that is www.spectrumpharm, spectrum P-H-A-R-M.com. And it is significantly different from the NeoTherapeutics Web site. So I would invite people to go and visit that site to get more information about products and the people here at Spectrum.

Rajesh Shrotriya: Thank you.

Operator: Thank you for participating in today s Spectrum Pharmaceuticals conference call. This call will be available for replay beginning at 4 o clock pm Eastern Standard Time today during 11:59 pm Eastern Standard Time on December the 16, 2002.

The conference ID number for the replay is 7110018. Again, the conference ID number for the replay is 7110018. The number to dial for the replay is 1-800-642-1687 or 706-645-9291. Thank you.

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.

SPECTRUM PHARMACEUTICALS, INC.

Date: December 19, 2002

By: /s/ Carol Gruetter

Name: Carol Gruetter
Title: Corporate Secretary