

PREDIX PHARMACEUTICALS HOLDINGS INC

Form 425

May 01, 2006

Filed by EPIX Pharmaceuticals, Inc.

Pursuant to Rule 425 under the Securities Act of 1933, as amended

Subject Company: Predix Pharmaceuticals Holdings, Inc.

Commission File Number: 000-51551

The following communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that are based on current expectations of the Company's management. These statements are neither promises nor guarantees, but are subject to a variety of risks and uncertainties, many of which are beyond the control of EPIX Pharmaceuticals, Inc. (EPIX) or Predix Pharmaceuticals Holdings, Inc. (Predix), and which could cause actual results to differ materially from those contemplated in these forward-looking statements. Such forward-looking statements include statements regarding: the anticipated successful closing of the merger including that it will result in a specialty pharmaceuticals company with therapeutic and imaging components and the expected timing and benefits thereof; the expectation that Michael J. Astrue will step aside as EPIX's interim Chief Executive Officer in early May and enter into a consulting agreement with EPIX to continue to advise EPIX through the solicitation of the shareholder vote to approve the merger and to assist in planning the integration of Predix into EPIX's operations; the belief that the S-4 filed with the Securities and Exchange Commission demonstrates the exciting nature of the combined company; the belief that the decision to operate EPIX since September 2005 with a number of temporary executives should make for a smoother integration of EPIX and Predix than what is typical in these situations; the hope that when shareholder approval of the merger is obtained, the combined company will be able to totally focus on clinical and business development progress, rather than organizational minutia; the belief that EPIX will not be able to get the FDA to commit to a special protocol assessment and, as a result, expects to ask the FDA to approve the NDA for Vasovist and ask that they include an advisory committee as part of the decision-making process; the belief that if the FDA grants the advisory committee meeting that it will occur in the second half of 2006 and the intent of EPIX in the meantime to consider the possibility of another clinical trial and discuss possible protocol with its partner, Schering AG; the expectation that Schering AG will not make its decision regarding its option of EP-2104 any earlier than late in this quarter; the intent to not open discussions with other companies regarding EP-2104 as long as EPIX hears from Schering AG within the timeframe it has to make its decision; the belief that if Schering AG does not exercise its option, EPIX will be able to license EP-2104 to another company on the same or better terms than it currently has with Schering AG; the belief that if Schering AG does not exercise its option, EPIX would likely repartner; the belief that, while the intent is to file an appeal, there is some possibility that there will be discussions that lead to a decision to do something other than pursue the appeal, or even to do a trial and the appeal in tandem; the belief that the team is substantially ready for the advisory committee appearance, if there is an advisory committee; the belief that EP-2104 will not likely go directly to a Phase III trial; the belief that the combined company will have an ambitious clinical program and ambitious business development agenda in the second half of the year and will likely try to enter partnerships as quickly as possible; the expectation that EPIX will file the appeal this quarter and that the FDA will respond either late in this quarter or early in the third quarter and that EPIX will then find out whether the FDA has granted an advisory committee meeting; the belief that EPIX made some progress with the FDA in some areas that it had not seen before; the expectation that the board of directors of the combined company will

approve its product pipeline no earlier than the fall of 2006; the expectation that a shareholder vote to approve the merger will occur in June or July 2006; and the expectation that at the end of the quarter the combined company will have approximately \$125 million which would, under conservative scenarios, give the combined company cash into 2008. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: costs related to the merger, failure of EPIX's or Predix's stockholders to approve the merger, EPIX's or Predix's inability to satisfy the conditions of the merger, the risk that EPIX's and Predix's businesses will not be integrated successfully, the combined company's inability to further identify, develop and achieve commercial success for new products and technologies, the possibility of delays in the research and development necessary to select drug development candidates and delays in clinical trials, the risk that clinical trials may not result in marketable products, the risk that the combined company may be unable to successfully secure regulatory approval of and market its drug candidates, the risks associated with reliance on outside financing to meet capital requirements, risks associated with Predix's new and uncertain technology, the development of competing systems, the combined company's ability to protect its proprietary technologies, patent-infringement claims, risks of new, changing and competitive technologies and regulations in the U.S. and internationally. You are urged to consider statements that include the words may, will, would, could, should, believes, estimates, projects, potential, expects, intends, continues, forecast, designed, goal, or the negative of those words or other comparable words to be uncertain and forward-looking. These factors and others are more fully discussed in EPIX's periodic reports and other filings with the SEC.

EPIX and Predix undertake no obligation and do not intend to update these forward-looking statements to reflect events or circumstances occurring after the date of this communication. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this communication. All forward-looking statements are qualified in their entirety by this cautionary statement.

THE FOLLOWING IS THE TRANSCRIPT OF THE CONFERENCE CALL WITH ANALYSTS, INVESTORS
AND OTHERS HELD ON MAY 1, 2006 AT 10:30 A.M.

Operator

Good day, ladies and gentlemen, and welcome to the first quarter 2006 EPIX Pharmaceuticals, Inc. earnings conference call. (OPERATOR INSTRUCTIONS). As a reminder, ladies and gentlemen, this conference is being recorded for replay purposes. I would now like to turn the presentation over to Ms. Hedison. You may proceed.

Amy Hedison - EPIX Pharmaceuticals, Inc. IR

Good morning everyone, and thank you for joining us on today's conference call. I have with me Mike Astrue, our interim Chief Executive Officer, and Bob Pelletier, our Chief Accounting Officer. Prior to turning the call over to Mike though I want to remind you that certain remarks that we may make about future expectations, plans and prospects for EPIX during this call constitute forward-looking statements for purposes of the Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995. Our actual results may differ materially from those indicated by these forward-looking statements, as a result of various important factors, including those that are discussed in our annual report on Form 10-K, our quarterly reports on Form 10-Q, and in our other SEC filings, which are on file with the SEC. Please refer to those filings for a complete description of these factors.

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Good morning, and thank you for joining us. One of the best feelings in life is to take on a tough challenge and then be able to say, mission accomplished. I am at that point with EPIX now, and I want to thank my Chairman, Chris Gabrieli, and my entire Board for the opportunity to lead EPIX into an exciting new chapter in its history. I also want to give my special thanks to the temporary team that joined me here, Phil Chase, Neil Kirby, Amy Hedison and Mike Gilman, for dropping what they were doing and working pedal to the metal. I also want to thank the holdover team led by Andrew Uprichard, for supporting me fully in a time of accelerated change in direction. And Sheila Dewitt for heroic work on our reverse auction process in closing the deal.

Having accomplished the mission it is time for me to step aside and begin pursuing other opportunities. I will remain at EPIX probably for just a few more days as I finish work on a couple of projects. I also expect to enter into a consulting agreement with EPIX that will allow me to continue to support the team soliciting the shareholder vote and to support planning for integration of Predix into EPIX operations. I have the utmost confidence in Andrew and the employees of EPIX as they lead the Company in the next few weeks prior to the consummation of the merger, and then as part of the combined Company following completion of the merger. I feel blessed to have been a part of this team.

In deciding to acquire a company as opposed to building a therapeutics capability organically, the EPIX Board of Directors has, in my opinion, widely taken advantage of the market diversion to Biotech IPOs, and as a result obtained a terrific company with valuable product candidates at a significant discount to its true value. The auction process we went through very much helped to insure that the Board had a wide variety of good choices, as well as the leverage to obtain the best price.

We filed the S-4 with the SEC last week. And I believe the filing demonstrates the exciting nature of the new combined Company. The Board's decision to operate the Company since September with a number of temporary executives should make for a smoother integration of the Company than what is typical in these situations. The market response to the merger has been positive to date, and we're hopeful that after shareholder approval, the combined Company will be totally focused on clinical and business development progress, rather than organizational minutia. Let me return now to EPIX programs. We did have a meeting to discuss Vasovist with the FDA in early April. While there were positive aspects to the meeting, particularly with regard to some apparent new flexibility in the area of trial design, it is clear to me that the standards for approval for imaging products are in such flex that we're not going to be able to get the agency to commit to a special protocol assessment. As a result, the Board has authorized an appeal in which we will ask the FDA to approve the NDA for Vasovist, and ask that they include an advisory committee as part of the decision-making process.

The timing going forward is somewhat uncertain. If we're granted the committee meeting, and the FDA is under no obligation I should point out to do so, we would expect that the meeting would occur in the second half of this year. The decision by the Board to pursue an appeal comes after many months of trying to work with the FDA to craft a mutually acceptable path to approval in the United States. In the meantime, we will continue to consider the possibility of another clinical trial and to discuss possible protocol with our partner, Schering AG.

Turning now to EP-2104, we have submitted our report to Schering. They have been reviewing the report in considerable detail. And I understand that a decision on the option is being discussed at the highest levels of Schering. I would not expect a decision from Schering any earlier than late in this quarter. And I can't predict what they're going to do, particularly in light of their acquisition by Bayer.

If I were in their shoes, I would exercise the option based on the strength of the data, but we will just have to wait and see. If Schering decides not to exercise its option, we believe that we will be able to license EP-2104 to another company on the same or better terms than we have currently as part of our partnership with Schering AG.

I'm not going to discuss the Predix program, other than comment that there are no changes to previously disclosed timelines, and to note that we were very pleased with the recent data in the Phase Ib PAH trial. Again, it has been an important eight months for EPIX and for me, and I'm delighted that the long-standing mission of becoming a specialty pharma Company with therapeutic and imaging components has been accomplished, and accomplished in fine fashion. Thanks again to everyone from Board members to employees to support of shareholders who have helped us along the way. I will now take any questions you may have.

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS). Dalton Chandler with Needham & Company.

Dalton Chandler - Needham & Company Analyst

Mike, congratulations on a job well done. We will miss you on future calls.

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Thank you.

Dalton Chandler - Needham & Company Analyst

Let me just ask about the advisory committee meeting. Can you talk about what this implies for the timing of a potential Phase III trial if you have to do that? I think you mentioned you would continue to consider it.

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Right. One of the things that happens in an appeal let me back up. As much as we have moved into perhaps a more binary situation, the appeal going forward, we're not currently moving ahead on a trial. One of the reasons I had couched the language a little bit more cautiously is that when you appeal a decision of the FDA, you're taking it up to a whole other level in the agency, people that are looking at this in a fresh light, who often have a very different perspective on things.

And there is often can be what is sort of the equivalent in the criminal process, plea-bargaining. That there are alternative approaches that are discussed that might conceivably be agreeable to the EPIX Board. I think we have been fairly clear that the Board's preference, rather than pursuing an appeal, was to try to find a mutually agreeable trial and wait and do that. That hasn't been possible. It doesn't look like it is possible right now. But on the other hand, we're going to be talking to more senior people with no real background as far as we know on these issues.

It may there is some possibility that there will be discussions that will lead to a decision to do something other than pursue the appeal, or even to do a trial and the appeal in tandem. Right now we're not planning on that, but those are possibilities. I think you have to stay nimble and flexible in these situations, particularly when the agency is being somewhat unpredictable. Right now I think investors should assume that the shot we're taking in the short run is on the appeal. As I have said before, we have been working diligently on this to be ready to do this if the Board determines that it wanted to. The team is substantially ready for the advisory committee appearance, if we get an advisory committee. The actual filing of appeals a fair amount of paper will take certain number of weeks to do, but should not take terribly long. We're going to pursue it as energetically as we can, but I think that the important thing is to continue to stay alert to other opportunities to see if there's some way to work this out with the agency.

Dalton Chandler - Needham & Company Analyst

Can you shed any light on what the sticking points may have been on the FDA?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

I think the fact that I can't answer that question with a great deal of particularity, illustrates what the problem is. We have pointed investors in the past to remarks that the FDA made in October in a public meeting that was webcast where essentially the agency, the person responsible for imaging, got up and said, we're rethinking everything in imaging. We're going to do things radically differently going forward. The old rules don't apply. And we need your help in devising what the new rules were going to be.

That was not particularly the timing of that message was not a good one from an EPIX point of view. And we approached the submission of a protocol with the hope that the agency might actually like to clarify certain things, not only for us, but for others, in the context of a very concrete protocol for a potentially important product.

That was really part of the hope that we had as we went through this process. Unfortunately, when we went into talk to them about it, if anything, it seemed to me that the submission of a protocol raised almost as many questions as it resolved. Again, I think we did make some progress in some areas that we had not seen before. But the submission of a protocol raised a bunch of new questions. And we really just couldn't get locked down from then in advance. We heard many times, well, do your trial, submit your data, and then we will see. And that was really not what we were looking to hear.

Operator

Ian Sanderson with Cowen & Company.

Ian Sanderson - Cowen & Company Analyst

First, do you know in terms of timeline on the appeal when you might hear from the FDA whether you will get an advisory committee meeting or not? And secondly, on just the relationship with Schering AG, is Schering playing a role here in the prosecution of Vasovist or are they really on the sidelines, given their pending acquisition by Bayer?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Those are good questions. I would say that timelines are a little fluid. It depends on when we submit our actual appeal, which as I said, is going to be a very lengthy and fairly specific document. But we will file that this quarter. I would think will get a response from the agency, technically possible, it could be late this quarter. It is probably more likely to be early in the third quarter. And then find out whether we're going to get the advisory committee meeting that we have requested.

With regard to Schering, I would say that their participation has been somewhat in between the two alternatives that you presented. They are following this very keenly. They get detailed reports after each of the FDA meetings. We have had discussions in steering committee and in other context about what we ought to do and how. And they are interested not only precise for Vasovist, but they have obviously got a big stake in imaging products generally, and are interested not only specifically for Vasovist, but for the various products they have that they are trying to push forward through registration, trying to figure out what the new roles of the game are.

I think they are interested in both levels. We have had pretty constant professional dialogue, but we are calling the shots on the strategy today.

Ian Sanderson - Cowen & Company Analyst

And then on EP-2104, would you be prepared to initiate a Phase III program there if Schering AG decides not to go forward? In other words, keep the ball rolling ahead of licensing it to somebody else?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

I don't think we're going to do that. I think the timelines are relatively short for Schering making their decision. I think that it would be appropriate for the Company to wait and see what Schering's stance is. I think that is required by good partnering anyway. We will we're not going to open discussions with other companies as long as we hear from Schering within the timeframe that they have to make this decision.

I would think it is probably not likely that we would go it won't be my decision it is not likely that we would go directly to a Phase III. This was a Phase IIa. I think it contemplated a IIb. It is what I would call an exploratory trial. We had six different groups of eight patients. I think that what this does is give you enough information to figure out which one or two trials you wanted which one or two indications are most promising, design the trials, so slightly bigger than 8 patients before you go into the Phase III.

And particularly with the FDA's standards in some flex, I think that you have to look at a IIb as sort of a dress rehearsal. They are going to be requiring it all likelihood some things they haven't required before. You want to make sure you know what that looks like in practice before you go to a pivotal trial.

Ian Sanderson - Cowen & Company Analyst

If Schering AG does decline the option though, would you be prepared to do that Phase IIb, or would you just wait till somebody else licenses the program?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

I think, again, it won't be my decision to make. If it were, I would wait. We have had expressions of interest from other companies. There is a relatively small group that would be appropriate partners for this, and I think we all know who they are. We have heard from a number of them.

I think that what we would try to do in all likelihood would be to repartner. I think the Company is going to have its hands full with a pretty ambitious clinical program as it is. It is going to be looking, I would imagine, not only with 2104, but one or two of the programs coming in from

Predix to try to offload some of the responsibility and cost of future trials on partners as quickly as possible. I think the combined Company is going to have a very exciting, but ambitious, business development agenda in the second half of the year.

Operator

(OPERATOR INSTRUCTIONS). [Dianna Montif] with Loomis Sayles.

Dianna Montif - Loomis Sayles Analyst

Can you just address how you expect to go about rationalizing the pipeline, or is that something that you have to wait until after the actual merger to discuss?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Sure. We would have to wait until after the actual merger. It won't be my decision. Those are decisions that in fact I would expect would need to be approved by the new combined Board. Right now everything that EPIX was doing and everything that Predix is doing is proceeding clinically in pretty much the same way that was intended six, 12 months ago. It is pretty much steady as she goes.

All biotech companies have to rationalize their pipelines from time to time, figure out the products that are of highest value. I wouldn't anticipate that we would see any of that until the new combined Board has a chance to consider these programs and see what it is going to do. It doesn't mean that they are going to stop doing anything necessarily. But that will be their choice, and I wouldn't expect that they would be making those kind of decisions any earlier than the fall.

Dianna Montif - Loomis Sayles Analyst

Can you just review the timeline real quickly. When does the vote actually occur?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

There is a certain amount of wobble because it is not entirely within our control. We have done the Hart-Scott-Rodino filing. We have done the S-4 filing with the SEC. The next critical point in the process is the SEC responds. Sometimes they don't respond at all. In recent years they are fairly likely to respond. When they respond, there tend to be quite a few comments, most of which are of a fairly minor and technical nature, but you need to go back and fix your documents, and go back and have an iterative process with them. It depends pretty much on when they respond and how much they say. If you assume that they do review it and there is the moderate amount of comments that we can work out with discussion, then we're looking at a June to July shareholder vote.

Operator

David Trump with [Corbin Investment Management].

David Trump - Corbin Investment Management Analyst

I what is like to know, is there some estimate of how much cash burn you're going to have going forward?

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

We have, with the S-4, put a lot of data in on what the financial situation of the combined Company will be. I think that the critical things are that after the vote we are anticipating that the combined Company will have approximately \$125 million. And that we would expect under most resemble conservative scenarios that we would be that would give the combined Company cash into 2008.

David Trump - Corbin Investment Management Analyst

Okay. Thank you.

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

I think for more detail you really ought to look at the S-4.

David Trump - Corbin Investment Management Analyst

Yes, I will do that. Thank you.

Operator

At this time there are no further questions in queue. I would like to turn the presentation back over to Ms. Amy Hedison for closing remarks.

Amy Hedison - EPIX Pharmaceuticals, Inc. IR

Thank you.

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Let me I've got one let me just correct one misspoken comment. I said cash of 125 at time of closing. I should have said cash at the end of the first quarter. I am sorry. I made a mistake on that. So please stand corrected on that. I will turn it back to Amy.

Amy Hedison - EPIX Pharmaceuticals, Inc. IR

Thank you everyone. Appreciate your questions and your interest, and we look forward to talking to again relatively soon we hope. Bye.

Mike Astrue - EPIX Pharmaceuticals, Inc. Interim CEO

Thank you all.

Operator

Ladies and gentlemen, I would like to thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. And have a wonderful day.

EPIX has filed a registration statement on Form S-4 with the Securities and Exchange Commission containing a joint proxy statement/prospectus in connection with the proposed merger with Predix Pharmaceuticals. Investors and security holders are advised to read the joint proxy statement/prospectus (including any amendments or supplements thereto) regarding the proposed merger because it contains important information about EPIX, Predix and the proposed transaction and other related matters. The joint proxy statement/prospectus will be sent to stockholders of EPIX and Predix seeking their approval of the proposed transaction. Investors and security holders may obtain a free copy of the joint proxy statement/prospectus and any amendments or supplements thereto (when they are available) and other documents filed by EPIX at the Securities and Exchange Commission's web site at www.sec.gov. The joint proxy statement/prospectus and such other documents may also be obtained for free by directing such request to EPIX Pharmaceuticals, Inc. 161 First Street, Cambridge, Massachusetts, Attn: Investor Relations, tel: (617) 250-6000; e-mail: ahedison@epixpharma.com or Predix Pharmaceuticals Holdings, Inc., 4 Maguire Road, Lexington, Massachusetts 02421, Attn: Investor Relations, tel: (781) 372-3260; e-mail: investors@predixpharm.com. EPIX and Predix and their respective directors, executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies with respect to the adoption of the merger agreement and the transactions associated with the merger. A description of any interests that EPIX and Predix directors and executive officers have in the merger is included in the registration statement containing the joint proxy statement/prospectus filed with the Securities and Exchange Commission and available free of charge as indicated above. Information regarding EPIX's executive officers and directors is also available in EPIX's Form 10-K, as amended, for the year ended December 31, 2005, which was filed with the Securities and Exchange Commission on March 1, 2006 and amended on April 28, 2006. You can obtain free copies of these documents using the contact information above.