

**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 Exchange Act of 1934**

Date of Report (Date of earliest event reported) **February 18, 2005**

SONUS PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

0-26866
(Commission
File Number)

95-4343413
(IRS Employer
Identification No)

22026 20th Avenue S.E., Bothell, Washington 98021
(Address of principal executive offices)

(425) 487-9500
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☒ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD disclosure

On February 21, 2005, an interview with Michael A. Martino (President & CEO of Sonus Pharmaceuticals, Inc.) will be published in The Wall Street Transcript. A transcript of this interview is attached hereto as exhibit 99.1.

Item 9.01 Exhibits

<u>Exhibit</u>	<u>Description</u>
99.1	Transcript of CEO interview printed in The Wall Street Transcript

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.

SONUS PHARMACEUTICALS, INC.

Date: February 18, 2005

By: /s/ Alan Fuhrman
Alan Fuhrman, Senior Vice President and
Chief Financial Officer

THE WALL STREET TRANSCRIPT

Questioning Market Leaders For Long Term Investors

Sonus Pharmaceuticals, Inc. (SNUS)



MICHAEL A. MARTINO is President, Chief Executive Officer and a Director of Sonus Pharmaceuticals Inc. Mr. Martino joined Sonus in September 1998 as President, Chief Operating Officer and a Director and was appointed Chief Executive Officer in July 1999. From 1983 to 1998, he held numerous positions of increasing responsibility in strategic planning, business development, marketing and sales, and general management with Mallinckrodt, Inc., a global healthcare products company, including serving as Vice President and General Manager of the Nuclear Division. Mr. Martino received a BA in Business from Roanoke College and an MBA from Virginia Tech. He sits on the Presidents Advisory Board of Roanoke College and is a member of the Board of Trustees of Cascadia Community College. In addition, Mr. Martino is a past Chairman of the Board of the Washington Biotechnology and Biomedical Association (WBBA).

(SAY232) TWST: It's been about a year since we were brought up to date on Sonus. What's happened over the past year or so that investors should focus on?

Mr. Martino: 2004 was a very busy year for Sonus. We presented continued strong clinical results from the Phase IIa trials of TOCOSOL Paclitaxel, our lead cancer drug in studies to treat solid tumors of the lungs, ovaries and bladder. That was peer-reviewed data that we presented at the American Society of Clinical Oncology (ASCO) Annual Meeting. During the year, we initiated a Phase IIb study of TOCOSOL Paclitaxel in a breast cancer indication, and we also received guidance from the FDA in December at an end of Phase II meeting, where they indicated it was appropriate for us to move to pivotal Phase III studies with TOCOSOL Paclitaxel. We are currently in discussions with them on the protocol for that trial. The FDA also indicated that it was appropriate for us to submit a TOCOSOL Paclitaxel New Drug Application under the 505(b)(2) regulatory mechanism, which potentially provides for accelerated development of the product.

We also significantly expanded our internal capabilities and expertise in 2004, including additions to our management team in the areas of clinical and regulatory development as well as product and corporate development with a focus on oncology. In addition, we announced the appointment of a new Chief Financial Officer. Finally, we completed a private equity financing in the middle of the year that raised \$14.4 million in net proceeds.

TWST: As far as the drug goes, what's the market it's serving? What sets it apart from what's already available in the marketplace?

Mr. Martino: The name of the drug is TOCOSOL Paclitaxel. It is a novel formulation of paclitaxel, the active ingredient in Taxol and other drugs approved for the treatment of solid tumors of the breast, lungs and ovaries. It's in excess of a \$2 billion market worldwide. What's unique about our drug is the combination of features and benefits, including convenience and ease of use, lower cost of use, and potentially better safety and efficacy. Of course, those last two points are contingent on our ability to prove them in controlled trials to FDA's satisfaction; however, we believe this combination of features, advantages and benefits will differentiate our drug.

COMPANY INTERVIEW

TWST: What is it that makes it easier to use?

Mr. Martino: We've applied a unique and proprietary delivery technology that we've trademarked TOCOSOL that utilizes vitamin E as a biocompatible solvent to formulate the drug and results in a ready-to-use formulation. The user will simply draw this out of a vial into a syringe and it's ready to administer. That eliminates 20 to 30 minutes of pharmacy preparation time required with other approved paclitaxel products and alternative formulations in development. Additionally, our drug can be administered in 15 minutes as compared to the three hours required with Taxol.

TWST: So it sounds like it has multiple advantages.

Mr. Martino: We believe it does, yes.

TWST: What is the timeline on this?

Mr. Martino: We have announced that we are in discussions with the FDA regarding the design of our proposed Phase III trial protocol. We know that it will be a single clinical trial. We know that it will require between 400 and 800 patients, and we've said that it will be in an indication for which Taxol is approved as a single agent. So it would either be in second line metastatic breast cancer or second or third line metastatic ovarian cancer. We expect to follow that discussion on trial design with a Special Protocol Assessment (SPA), which is an agreement with the FDA on the details of our Phase III program. The FDA has encouraged us to seek that, and we think that's great news. Depending upon the length of our discussions with the FDA to finalize the SPA, we would expect to be in a position to initiate a pivotal trial by the end of Q2 this year. That may be aggressive, but certainly in Q3.

TWST: So not that far down the road?

Mr. Martino: No, it's really not.

TWST: Given what's going on with Vioxx, etc., is the FDA trying to be as aggressive in pushing things through as they were before?

Mr. Martino: Vioxx and the other COX-2 inhibitors are reviewed by a different division in FDA and treat different diseases or conditions. Every indication that we've received is that FDA is being very responsive in reviewing the material that we send to them and following through with their guidance and feedback. Of course, it's always difficult to predict these things.

TWST: But so far, so good?

Mr. Martino: So far, so good.

TWST: Assuming approval, how would you go about marketing the product?

Mr. Martino: We are in discussions with prospective corporate partners for TOCOSOL Paclitaxel. We are looking for them to provide at least some of the resources, both capabilities and funding, to complete the remaining clinical development, and then we would look for those partners to commercialize the product. It would be our desire to retain co-promotion and co-marketing rights at least in the United States. It remains to be seen if we can do that. The primary strategy is to commercialize the product in collaboration with a partner that has existing sales and marketing capabilities and infrastructure in oncology.

TWST: So you're not going to go the whole route of setting up your own sales team.

Mr. Martino: That certainly is within our vision someday. Another major milestone in 2004 is that we announced the proposed acquisition of a French-based company by the name of Syntem that has interesting and proprietary technology utilizing small peptides to provide for the delivery of pharmaceutical agents. In addition, we believe that the Syntem technology may be compatible with the Sonus TOCOSOL platform. This acquisition will give us multiple product opportunities in oncology and in pain management, specifically pain related to cancer. We anticipate closing the acquisition in April of this year. With those combined capabilities and the pipeline, in fact, we believe that this acquisition would put us in a much stronger position to some day realize our vision of being a specialty pharmaceutical company with our own sales and marketing infrastructure.

TWST: Are you finding interest among potential partners?

Mr. Martino: We are finding interest. We are in ongoing discussions. Of course, it will be difficult to relay much of the specifics of those discussions before actually

having an agreement, however, I am very optimistic and encouraged that partnering discussions will converge with our FDA discussions to finalize the TOCOSOL Paclitaxel Special Protocol Assessment, so that we will have a partner signed up by the time that we want to initiate the Phase III trials.

TWST: What else is in the pipeline?

Mr. Martino: In the Sonus pipeline, we have a couple of additional product candidates, one that consists of a family of camptothecin derivatives. Camptothecin is another chemotherapy drug. We have applied our TOCOSOL technology to this drug as well. We believe in a way that will impart some similar benefits to what we are seeing with paclitaxel. In other words, we could have a camptothecin drug that is potentially more convenient, easier to use, safer and more active.

The camptothecin derivatives are currently in preclinical studies and our objective is to move a product candidate to an IND by the end of this year. Conceivably, that could be in Phase I trials by early next year.

In addition, the acquisition of Synt:em brings us at least two products in the later stages of preclinical studies, both in areas of pain management. These products are in very large markets and have been developed with novel approaches that, by the way, we think could avoid some of the toxicity issues associated with other commercialized pain products, such as morphine or COX-2 inhibitors. One of those products we believe will be ready to move into Phase I trials in the second half of 2005. The second one could be ready to move into Phase I trials by early 2006.

When you add all of that together, a year from today we could be a company with a Phase III cancer drug nearing the end of patient enrollment with a partner signed up to commercialize that product and two to three additional products — all addressing very large markets with significant unmet needs — in Phase I clinical trials.

TWST: You've got an awful lot going on. Do you have the team in place you need to handle all this?

Mr. Martino: That's always the challenge, of course, in a small company — managing available resources — and that includes people, time, and money for the best use against opportunities. We have assembled a strong, yet lean, team at Sonus. Right now we have about 50 employees. When you look at our burn rate with everything we have going on internally, it is still about \$1.2 million to \$1.5 million a month and that's a pretty efficient rate compared to some of our competitors. Additionally, we believe that Synt:em will bring us some significant capabilities in the form of people and know-how as well.

TWST: You mentioned the fundraising. Is that just to support ongoing operations?

Mr. Martino: Any time you are a small company with aggressive visions and plans, you are always in the fund raising mode. Now, having said that, we concluded Q3 of 2004 with about \$25 million in cash and no debt. The guidance for our burn rate in Q4 was \$1.2 to \$1.5 million a month, so a year-end 2004 cash balance of about \$20 million is a pretty good guideline. Our preferred financing strategy is to stay the course with TOCOSOL Paclitaxel, get agreement with FDA on the Special Protocol Assessment, conclude a partnership, and then use those events as the basis to strengthen the balance sheet.

TWST: Can you make it from here to there?

Mr. Martino: We think we can. It's a management challenge, but we think we can.

TWST: Why go that route as opposed to looking for partners earlier or selling off a piece of it?

Mr. Martino: That's the decision we've made with TOCOSOL Paclitaxel all along the way. We've had opportunities to partner the product earlier, but we were always able to get the financing we needed to take it to the next level of development and value creation. We believed that this strategy was in the best interest of our shareholders in the long term, and philosophically, we believe the product will never be as important to a partner as it is to us. As long as we could finance our way to that next step of value, we felt that was the right thing to do. We are clearly at a point where the TOCOSOL Paclitaxel Phase III trial is going to be a major undertaking, and we think the time is right now to conclude a partnership.

TWST: Are investors paying any attention to the success you are having?

Mr. Martino: We think they are. Over the past couple of months, we've had some announcements including the fact that number one, we had a very successful end of Phase II meeting with FDA in which we validated our regulatory strategy and we announced that via an 8-K filing. Based on that success, we also went back and renegotiated the terms of the proposed acquisition of Synt:em, resulting in an agreement that we think provides more favorable economics for our shareholders by retaining the near-term upsides related to TOCOSOL Paclitaxel.

And finally, we announced more recently that FDA has granted an orphan drug designation to go with a fast track designation that they granted earlier for TOCOSOL Paclitaxel for the treatment of transitional cell carcinomas, which are mostly solid tumors of the bladder. Since making these announcements, we've seen some nice appreciation in our stock price, and we've had significant interest expressed by people who want to make new investments. We're not where we want to be, of course, but I believe that Wall Street is showing interest in our progress.

TWST: When you talk to investors at this point, what's the prime question that they are asking you?

Mr. Martino: The prime questions relate to the level of our confidence in, one, securing the Special Protocol Assessment from FDA on TOCOSOL Paclitaxel and what that will mean relative to the required trial — number of patients, time, cost. Secondly, the interest is in what that will mean relative to our ability to secure a corporate partnership.

TWST: So that's kind of the focus of investors at this point?

Mr. Martino: I think appropriately so because those remain the number one priorities for the management team as well and are the key drivers for us over the next six to nine months.

TWST: If you were sitting down as you have with potential investors, what are the two or three reasons that you would give them today to take a look at the company?

Mr. Martino: There are several. The first is that we have a lead drug that addresses a very large market with significant unmet needs where the data we've generated to date suggests that we have a good opportunity to meet or exceed those needs. That drug is ready to begin Phase III clinical trials and we are pursuing agreement with FDA that will lock in what we need to do in those trials. So we believe that we've driven a lot of the clinical and regulatory risk out of the development of this product. Second, we have a proprietary technology platform with multiple product opportunities in large markets that would be complemented and expanded quite nicely with the proposed acquisition of Synt:em.

TWST: Thank you.

ADDITIONAL INFORMATION ABOUT THE SYNT:EM ACQUISITION

Sonus will file a proxy statement and other documents concerning the proposed acquisition of Synt:em with the Securities and Exchange Commission. SONUS STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT WHEN IT BECOMES AVAILABLE AND OTHER RELEVANT DOCUMENTS FILED WITH THE SEC BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. A copy of the proxy statement will be mailed to the stockholders of Sonus. Sonus stockholders may obtain a free copy of the proxy statement and other relevant documents filed by Sonus with the SEC when they become available at the SEC's Website. The proxy statement and these other documents may also be obtained for free from Sonus by directing a request to: Investor Relations, 22026 20th Avenue S.E., Bothell, Washington, 98021, telephone number (425) 487-9500.

Sonus and its directors, executive officers and certain of its employees may be deemed to be participants in the solicitation of proxies from the stockholders of Sonus with respect to the proposed transaction. Information regarding the names, affiliations and interests of the participants in the solicitation will be included in the proxy statement.

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