# 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) **May 9, 2005**

# SONUS PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

| **Delaware** | **0-26866** | **95-4343413** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (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 2.02 Results of Operations and Financial Condition.**

On May 9, 2005, Sonus Pharmaceuticals, Inc. issued a press release announcing its financial results for the fiscal quarter ended March 31, 2005. A copy of the press release making this announcement along with a transcript of the conference call are attached hereto as Exhibits 99.1 and 99.2, respectively and are incorporated herein by reference. The press release and the conference call transcript shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933.

**Item 9.01 Financial Statements and Exhibits.**

Exhibit 99.1 Press Release, dated May 9, 2005, issued by Sonus Pharmaceuticals, Inc.

Exhibit 99.2 Transcript of Sonus Pharmaceuticals, Inc. first quarter 2005 conference call.



**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: May 10, 2005

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



**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| Exhibit 99.1 | Press Release, dated May 9, 2005, issued by Sonus Pharmaceuticals, Inc. |
| Exhibit 99.2 | Transcript of Sonus Pharmaceuticals, Inc. first quarter 2005 conference call. |

NEWS RELEASE

*CONTACT: Pamela L. Dull, Sonus Pharmaceuticals, Inc., (425) 487-9500, Ext. 255*

**Sonus Pharmaceuticals Reports First Quarter Progress and Financial Results**

***Quarterly conference call today at 1:30 P.M. PDT/4:30 P.M. EDT***

**BOTHELL, Washington, May 9, 2005—**Sonus Pharmaceuticals, Inc. (Nasdaq:SNUS) today highlighted progress and reported financial results for the first quarter ended March 31, 2005.

"In the first quarter, we remained focused on the implementation of our strategy for TOCOSOL® Paclitaxel, and we are making good progress toward realizing our goal of performing the Phase 3 pivotal trial," said Michael A. Martino, President and CEO of Sonus Pharmaceuticals. "We are eager to confirm the potential advantages of TOCOSOL Paclitaxel, and believe we are squarely on track with a Phase 3 development program that will position our product competitively in the attractive and growing taxane market."

**First Quarter 2005 Highlights**

- Continued in discussions with the U.S. Food and Drug Administration (FDA) to reach agreement on the Special Protocol Assessment (SPA) for the Phase 3 trial of TOCOSOL Paclitaxel. Based on discussions to date, the company's goal is to finalize the SPA by the end of the second quarter of 2005. However, Sonus cannot manage the content or timing of FDA decisions or actions.
- Met with the FDA in March to review the Chemistry, Manufacturing and Controls (CMC) information that will support the New Drug Application (NDA) for TOCOSOL Paclitaxel. The FDA agreed that the current CMC information is sufficient to initiate Phase 3 testing and that the data which the company intends to include in its NDA would be sufficient for FDA review of that application.
- Continued progress in the Phase 2b study of TOCOSOL Paclitaxel in metastatic breast cancer. To date, the investigator-reported response rate in this group of patients is at least 51% after 16 weeks of treatment. At present, data reporting is incomplete and ongoing as the study continues. However, the company plans to submit results for presentation at the San Antonio Breast Cancer Symposium in early December, including confirmed objective response rate, estimated median time to disease progression, and safety data.

More

---

- Received notice that the American Society of Clinical Oncology (ASCO) selected a TOCOSOL Paclitaxel abstract for poster presentation at its annual meeting to be held in Orlando, Florida, May 13-17. Sonus will present data from a clinical pharmacology study of TOCOSOL Paclitaxel and Taxol® conducted in 2004. This study included analyses of the amounts of paclitaxel in the blood circulation following single doses of TOCOSOL Paclitaxel and Taxol, and results showed that TOCOSOL Paclitaxel delivered substantially more active paclitaxel into circulation. Full results of the study will be available at ASCO.
- Continued to monitor the long-term value of treatment with TOCOSOL Paclitaxel in the Phase 2a trials of ovarian, non-small cell lung and bladder cancers that began in 2002 and completed patient enrollment in mid-2003. Maturing data on survival duration indicate that, following second-line treatment with TOCOSOL Paclitaxel, median survival in each study is estimated to be similar to published results for combination chemotherapy regimens used in the treatment of these types of cancer.

**First Quarter Financial Results**

For the first quarter of 2005, the company reported a net loss of $4.8 million, or $0.22 per share, compared with a net loss of $3.6 million, or $0.20 per share, in the first quarter of 2004. The planned higher net loss primarily reflected increased R&D spending to support additional clinical studies for TOCOSOL Paclitaxel as well as higher G&A costs related to business development activities and the termination of the Synt:em acquisition. Cash and marketable securities totaled $15.1 million at March 31, 2005.

**Quarterly Conference Call**

Sonus will host its quarterly conference call today, Monday, May 9, at 1:30 P.M. Pacific Time/4:30 P.M. Eastern Time. The call will be web cast live and archived on the company's web site at www.sonuspharma.com/events.html. A telephone replay of the conference call will also be available for one week at (800) 642-1687 or (706) 645-9291 for international calls; Conference ID 5671724; Pass code 010315.

**About Sonus Pharmaceuticals, Inc.**

Headquartered near Seattle, Sonus Pharmaceuticals is focused on the development of therapeutic drugs that may offer improved administration, safety, tolerability and effectiveness for the treatment of cancer and related indications. The company's lead product candidate is TOCOSOL Paclitaxel, a novel formulation of the widely prescribed anti-cancer drug paclitaxel. TOCOSOL Paclitaxel has been designed to overcome the limitations associated with Taxol and generic paclitaxel-based chemotherapy, including long infusion times, undesirable or treatment-limiting side effects as well as time consuming and expensive preparation prior to administration. Sonus is currently in discussions with the FDA to finalize the Special Protocol Assessment agreement for the pivotal Phase 3 trial of TOCOSOL Paclitaxel, which the company expects to initiate in 2005. For additional information about Sonus, including past news releases, please visit www.sonuspharma.com.



---

**Safe Harbor**

Certain statements made in this press release are forward-looking such as those, among others, relating to the development, safety and efficacy of drug delivery products and potential applications for these products or the anticipated date of the initiation of Phase 3 clinical trials for TOCOSOL Paclitaxel. As discussed in Sonus Pharmaceuticals' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed on March 23, 2005, actual results could differ materially from those

projected in the forward-looking statements as a result of the following factors, among others: the company's products will require extensive clinical testing and approval by regulatory authorities; such approvals are lengthy and expensive and may never occur; risks that the company will not be able to initiate Phase 3 clinical trials for TOCOSOL Paclitaxel; risks that clinical studies with TOCOSOL Paclitaxel will not be successful; risks that the FDA may not approve the company's proposed New Drug Application; risks of successful development of additional drug delivery products; and risks that the company may not be successful in obtaining funding from third parties or completing a financing necessary to support the costs and expenses of clinical studies as well as research and development activities. The company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.

###



**Condensed Statements of Operations**
**(Unaudited)**
**(in thousands, except per share amounts)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2005 | 2004 |
| | $ — | $ — |
| Revenue | | |
| Operating expenses: | | |
| Research and development | 3,123 | 2,568 |
| General and administrative | 1,743 | 1,046 |
| Total operating expenses | 4,866 | 3,614 |
| Operating loss | (4,866) | (3,614) |
| Other income, net | 91 | 36 |
| Loss before taxes | (4,775) | (3,578) |
| Taxes | — | — |
| Net loss | $ (4,775) | $ (3,578) |
| Net loss per share: | | |
| Basic | $ (0.22) | $ (0.20) |
| Diluted | $ (0.22) | $ (0.20) |
| | | |
| Shares used in calculation: | | |
| Basic | 21,354 | 18,046 |
| Diluted | 21,354 | 18,046 |

**Condensed Balance Sheets**
**(in thousands)**

| | March 31, 2005 (unaudited) | December 31, 2004 |
|---|---|---|
| Assets: | | |
| Cash and marketable securities | $ 15,139 | $ 20,580 |
| Other current assets | 284 | 459 |
| Property and equipment, net | 1,366 | 1,480 |
| Other assets | 52 | 52 |
| Total assets | $ 16,841 | $ 22,571 |
| | | |
| Liabilities and stockholders' equity: | | |
| Accounts payable and accrued expenses | $ 2,237 | $ 3,177 |
| Lease obligations | 80 | 121 |
| Deferred rent | 180 | 196 |
| Stockholders' equity | 14,344 | 19,077 |
| Total liabilities and stockholders' equity | $ 16,841 | $ 22,571 |

Taxol® is a registered trademark of Bristol-Myers Squibb Company.

**MANAGEMENT DISCUSSION SECTION**

Operator: Good afternoon, my name is Michael and I will be your conference facilitator today. At this time I would like to welcome everyone to Sonus Pharmaceuticals First Quarter Conference Call. [Operator Instructions] Thank you. Miss Dull, you may begin your conference.

**Pamela L. Dull, Director of Investor Relations**

Thank you Michael, and good afternoon everyone. Welcome to Sonus Pharmaceuticals First Quarter Conference Call. I am Pamela Dull, Director of Investor Relations. To begin the call, I'd like to remind everyone that some of the statements made today may include predictions, estimates and other information that might be considered forward-looking. These statements are based on current expectations and assumptions that are subject to risks and uncertainties. Actual results could differ materially from our predictions and estimates, as a result of various risk factors, including those identified in our Form 10-K for the year ended December 31, 2004, and other SEC filings, all of which can be accessed on our website.

With that, I'll turn the call over to Mike Martino, President and CEO of Sonus.

**Michael A. Martino, President, Chief Executive Officer and Director**

Thanks, Pam. Hello and welcome everyone. Joining Pam and me on today's call are Alan Fuhrman, our Chief Financial Officer and Dr. Michael Stewart, our Chief Medical Officer. Since we last talked with you a short eight weeks ago, we've moved steadily forward with the implementation of our strategy for TOCOSOL Paclitaxel, and I believe that we are on track to achieve our objective. We're focused on moving TOCOSOL Paclitaxel into a pivotal Phase III trial in 2005, and have made good progress on that objective. We've had further substantive discussions with the FDA to finalize the Phase III Special Protocol Assessment, or SPA, and I'm delighted to report that we now believe we have a clear path to complete that process. We'll get into the details on that in a few minutes.

We'll use the following format for today's call. First, Alan will provide a brief summary of our financial results. Next, I'll review our first quarter progress. Michael will then review the status of our clinical and regulatory programs for TOCOSOL Paclitaxel, and finally we'd be happy to answer any questions you may have. With that, I'll now turn the call over to Alan.

**Alan Fuhrman, Senior Vice President and Chief Financial Officer**

Thank you, Mike. Let me briefly review the financial results for the quarter, which we reported in our press release this afternoon. We reported a net loss of $4.8 million or $0.22 per share for the first quarter of 2005, compared to a net loss of $3.6 million or $0.20 per share for the first quarter last year. The planned higher net loss primarily reflected an increased level of R&D spending, as we continue to execute the clinical and regulatory plans for TOCOSOL Paclitaxel, as well as higher G&A costs related to business-development activities, and the termination of the Synt:em acquisition.

On the balance sheet, we ended the quarter with 15.1 million of cash and no debt. We continue to expect that our cash burn during the first half of 2005 will be 1.5 million per month on average, increasing to approximately 1.6 million per month on average for the full year. However, this base burn rate does not include the costs of the Phase III pivotal trial for TOCOSOL Paclitaxel. As you know, our goal is to secure a corporate partner for TOCOSOL Paclitaxel to fund all or a portion of our Phase III trials. Once we have that partnership in place, we will be able to provide additional





guidance on the cost of the Phase III study for Sonus as it relates to our projected 2005 cash burn. I also want to note that, as previously announced, we filed an S3 shelf registration statement on April 1st of this year. The SEC has recently cleared the S3, and the only step remaining for the S3 to become effective is for Sonus to send the SEC a letter requesting acceleration.

That completes the financial overview, and I'd like to turn the call back to Mike.

**Michael A. Martino, President, Chief Executive Officer and Director**

Thanks, Alan. Let's move right into the highlights of our first-quarter progress. First, we continue the dialog we engaged with the FDA at our December 2004 end of Phase II meeting, and proceeding through the SPA process that began earlier this year for our Phase III registrational trial. In addition to the study protocol, an SPA includes agreements about how the study will be conducted, how end points will be evaluated, and how results will be analyzed statistically. In our SPA application, we also asked the FDA to agree on the basis for approval of our NDA, based on this pivotal study, with supportive data from our other clinical and non-clinical studies. As we've mentioned in the past it typically takes up to six months to get an SPA in place. At this point in our discussions with the FDA we are hopeful of meeting our goal of securing the SPA approval by the end of the second quarter.

Second, we had mentioned on our last update that we had a successful meeting with the FDA in March about the Chemistry Manufacturing and Controls (or CMC) information that will support the NDA for TOCOSOL Paclitaxel. The CMC information essentially details the product, its specifications, including stability as well as our processes and methods for manufacturing it in a repeatable, predictable, and reliable manner, within those specifications. We were delighted with the outcome of this important meeting, as the FDA agreed that the manufacturing process, analytical methods and stability testing programs for TOCOSOL Paclitaxel are sufficient to initiate Phase III testing and that the data we intend to include in our NDA would be sufficient for FDA review.

Third, during the first quarter we continued to evaluate the anti-tumor response rate and safety data from our Phase IIb study of TOCOSOL Paclitaxel, in patients with metastatic breast cancer, and those results are fully in line with our expectations. Michael will go into a little more detail in a moment.

Fourth, as you know, we completed patient enrolment in the Phase IIa studies of TOCOSOL Paclitaxel almost two years ago and those studies generated encouraging, initial data on safety and anti-tumor activity. We have continued to follow patients for survival duration in those studies and were pleased to have an update on those results today, which Michael will also cover in just a few minutes.

Finally, in the first quarter we continued in our discussions with prospective partners for TOCOSOL Paclitaxel. As we've previously indicated, our overall goal has been and remains to maximize the value of TOCOSOL Paclitaxel. A good corporate partnership or partnerships are a means to this goal. We believe that completing the Phase III SPA agreement with FDA in parallel with corporate partnership discussions puts us in a stronger position to realize appropriate value around the terms of the deal. Our goal remains to finalize the SPA and to secure a partner in order to initiate the Phase III trial for TOCOSOL Paclitaxel.

Let me say that we are pleased with the nature and progress of our partnership discussions. We are also at the stage where it is important not to presume the details of the outcome until the terms are finalized. I will now turn the call over to Michael Stewart, to provide further details on the clinical and regulatory progress with TOCOSOL Paclitaxel. Michael?



**Michael B. Stewart, Senior Vice President and Chief Medical Officer**

Thanks Mike. As Mike mentioned, we've had ongoing interactions with the FDA on our registrational Phase III trial plan. We submitted a request for special protocol assessments including the study protocol and formal written plans for how the study will be conducted, how study-specified end points will be evaluated, and how results will be analyzed statistically. Securing an SPA agreement is a complex process, but we continue to be pleased with the content and speed of our progress with FDA. The communications have been straightforward, and we believe that all details remaining to be finalized are understood, and that final agreement will be confirmed before the end of the second quarter. As we've previously stated, we do not control the timing of FDA review, or their response on any specific issue. As also previously stated, we believe it is most appropriate to wait for the final agreement before discussing publicly the design of the study.

We have chosen to invest the time required to secure this SPA agreement with the FDA before starting enrollment, in order to potentially reduce the regulatory review issues that are commonly encountered in review of an NDA submitted without an SPA agreement. When we submitted our SPA application to the agency we also asked them to address the proposed basis of approval for our NDA. They've indicated that approval of our NDA, under 505b2, would be based on the results of the single Phase III study that we will conduct, along with supportive data from our other clinical and non-clinical studies, and CMC information. It could also be related to modification of the current paclitaxel label to include a weekly dosing schedule, but based on our discussions with the FDA, we do not believe that would affect the timing of our NDA submission, nor the period of time required for its review.

We've also continued to make progress in the ongoing Phase IIb study in breast cancer. Data continue to come in, and both for anti-tumor responses and for tolerability of TOCOSOL Paclitaxel, which is being given weekly at a dose of a 120 milligrams per square meter, in the trial. At this point the investigator-reported response rate is at least 51% after 16 weeks of treatment, with a current 95% confidence interval of 36% to 66%. Data continued to come into the database every week, as monitoring of study sites and collection as report forms progresses. The CT scans obtained on each patient at eight week intervals, to assess response, and the confirmatory CT scans obtained four weeks after each response is identified are being transferred to an independent radiologist for review. We expect that we will have final, independently confirmed response assessments, more complete safety data, and an initial estimate of time to disease progression in time for presentation at the San Antonio Breast Cancer Symposium in early December of this year.

Turning to the ongoing Phase IIb study in bladder cancer, progress has continued to be slow in the U.S., because fewer and fewer patients are being referred to cancer centers for second line treatment of this disease. That pattern of practice started a few years ago, and has continued to develop in the U.S. It is different in Europe where many patients continue to be sent to large, specialized cancer centers. Regulatory approvals for our study are in the final steps in Spain and the U.K., and we will begin enrolling patients in about a half dozen centers there, in the next several weeks. Because this is a relatively rare disease, as we have discussed before, progress is not rapid. But, we continue to believe it is an important area where effective, more tolerable treatment is needed, and TOCOSOL Paclitaxel appears to offer a meaningful alternative to currently used therapy.

Next, as Mike mentioned a few minutes ago, we continue to monitor the long-term value of treatment with single agent TOCOSOL Paclitaxel in the Phase IIa trials of ovarian, non-small cell lung, and bladder cancers that began in 2002, and completed enrollment in mid-2003. All consenting patients have continued to be monitored through their treating physician, and we expect to have final data on all available patients before the end of this year. Data review, confirmation, and analyses are ongoing, and databases have not yet been locked, but median survival in each



of the three studies have now been estimated based on information reported by the investigators as of early May.

In the ovarian cancer study, median survival is estimated to be 74 weeks, with a 95% confidence interval of 49 to 116 weeks. In the non-small cell lung cancer study median survival appears to be 35 weeks, with a 95% confidence interval of 19 to 48 weeks. In the bladder cancer study, we are currently estimating median survival at slightly longer than 57 weeks, with a 95% confidence interval of 27 to 95 weeks. We believe these numbers for median survival, following treatment with TOCOSOL Paclitaxel are in each case in the ballpark of published survival duration after combination chemotherapy regimens used in the second line treatment of patients with these diseases.

Finally, as a reminder, I'd like to mention that the results of a clinical pharmacology study conducted last year, comparing TOCOSOL Paclitaxel and Taxol, will be presented at the upcoming ASCO Annual Meeting on Sunday, May 15 at 8:00 AM. This study included analyses of the amounts of Paclitaxel in the circulation over time following single doses of TOCOSOL Paclitaxel, and Taxol. Both drugs were administered as a standard Taxol regimen of 175 milligrams per square meter, separated by at least three weeks. This is one of the most comprehensive studies ever done for paclitaxel pharmacokinetics, and we look forward to sharing the full results of ASCO. As we have previously disclosed, the results show that the TOCOSOL formulation is able to deliver substantially more unbound; or active paclitaxel into the circulation over time, than it's achieved with Taxol. It is our belief that greater anti-tumor activity may results from treatment with TOCOSOL Paclitaxel, as the result of higher exposure to active drugs given on a sustained basis, and we look forward to confirming this hypothesis in our pivotal Phase III trial.

Mike, I'll turn the call back to you now.

**Michael A. Martino, President, Chief Executive Officer and Director**

Thank you, Michael. This is outstanding progress. We're excited to be moving closer to realizing our goal of performing the Phase III registrational trial for TOCOSOL Paclitaxel. We're eager to confirm the potential benefits of the product, and believe that our development program has the potential to differentiate TOCOSOL Paclitaxel from other products in this class, and to increase its value to cancer patients, physicians, and shareholders. Our strategy remains to position TOCOSOL Paclitaxel as the "Taxane of Choice", in an attractive and growing market, and I believe that we are squarely on track to implement this strategy.

Before wrapping up, let me quickly summarize expected milestones with TOCOSOL Paclitaxel for the balance of this year as follows. Complete the SPA process, secure a corporate partner, initiate the pivotal Phase III trial, predicate it on completion of the SPA process, and on available resources.

That completes our prepared remarks, and we'd be pleased to answer any questions that you may have. Michael, would you please open the line for questions?



- QUESTION AND ANSWER SECTION

Operator: Thank you. [Operator Instructions]. Your first question comes from Matt Kaplan.

**<Q – Matthew Kaplan>:** Good afternoon, guys.

**<A>:** Hi, Matt.

**<A>:** Hello, Matt.

**<Q – Matthew Kaplan>:** Just a quick question in terms of the progress towards the start of the initiation of the Phase III trial. Previously you had indicated that it was a third quarter goal for the company; is that still the case, and is that still achievable?

**<A – Michael Stewart>:** That remains our goal based on discussions to date with FDA we believe that is achievable. However, as Michael has said, we don't control, nor can we manage, the pace or the content of FDA's responses. So we'll be in a better position once we have the FDA finalized. So we believe, as of now, we're on track to do that by the end of June. But that, again, depends upon both the pace and content of our interaction with FDA.

**<Q – Matthew Kaplan>:** Sure. That's obviously hard to you to predict the bureaucracy. But with respect to, are there any issues or things you can point to that are holding off the FDA process? Or any —?

**<A – Michael Martino>:** No. It's really proceeding as we expected. I think the difficulty for business people is we're used to a business environment where we can have informal discussions and move forward very quickly from there. The process of interacting with FDA is a very stylized and formalized one. I want to say that we continue to be very pleased, as Michael said, with both the content and pace of those discussions, but we simply have no way of predicting that that will continue.

**<Q – Matthew Kaplan>:** And just a final question and then I'll jump back in the queue. In terms of your partnership discussion, it seems as though — have things — has the pace of discussions or the content of discussions there changed over the last quarter? Is there progress being made there that that's tangible? Or can you give us any sense?

**<A – Michael Martino>:** Well, I think there's very good progress being made there and those discussions have changed in terms of both pace and complexity from the perspective that we continue to be in discussions with people that have been at the table for a while and those discussions have picked up pace. And in addition, as we signaled, I believe, in our last call about eight weeks ago, we've had new people expressed interest and that has continued to occur, in fact, since that call eight weeks ago. So we continue to understand that concluding our first partnership in a major geography is a priority for shareholders, it remains a priority for us as well and I think we're making good progress towards that goal.

**<Q – Matthew Kaplan>:** Thank you.

**<A – Michael Martino>:** Thanks Matt.

**<A – Michael Stewart>:** Thank you Matt.

Operator: Your next question comes from Vinny Jindal.

**<Q – Vinny Jindal>:** Hey guys, its Vinny.



**<A – Michael Martino>:** Hi Vinny.

**<Q – Vinny Jindal>:** Mike Martino, I had a quick question for you regarding the pace of the negotiations with the potential partners. Roughly how much longer, based on the pace of the current discussions and how close you guys are in terms with the more serious potential partners, ballpark, how long after you get an SPA in place, would you at least expect to have a final deal done with a partner?

**<A – Michael Martino>:** Well Vinny, unfortunately, I think the best answer I can give you at this point is what I said in the conference call. I believe we're at the stage of discussions where it simply does not serve us well for me to speculate on that. I want to reiterate that I think we're making good progress and we are confident that that is an objective that we will meet, and one that we will meet to put us in a position to initiate the Phase III trial on schedule.

**<Q – Vinny Jindal>:** Fair enough, and not to put words in your mouth at all, but if it was on the order of, say, two months or something, that wouldn't be unexpected?

**<A – Michael Martino>:** Well, I really don't want to bite on the timing aspect of it, except to repeat again, that I think we're on a pace to put us in a position to initiate the Phase III trial on schedule, and conclusion of a partnership is a necessary ingredient.

**<Q – Vinny Jindal>:** Fair enough. And I have another question for Michael Stewart actually.

**<A – Michael Stewart>:** Yes?

**<Q – Vinny Jindal>:** Michael, roughly, what is the general response rate that's out there for Taxol used once weekly?

**<A – Michael Stewart>:** For?

**<Q – Vinny Jindal>:** In metastatic breast.

**<A – Michael Stewart>:** I think that you have to look at whether it's first line or second line. Probably the largest study that has been reported recently was one done by the CALGB that Dr. Andy Seidman from Memorial reported orally last year at ASCO, and in that study, which was a comparison of weekly Taxol versus Taxol used on the labeled regiment of 175 every 3 weeks. The patients who were assigned to receive weekly Taxol, about 80% of them, I recall, 75% or 80% were first line patients and the others were second line, so it was a mixed population. But overall, they had about a 40% response rate, which is what you would expect if you look at Phase II studies of smaller populations. 40% in first line disease, 30% in second line disease is not unreasonable.

**<Q – Vinny Jindal>:** And given that mix, how do you explain the roughly 25% increase in response rate that you're seeing with the TOCOSOL formulation?

**<A – Michael Stewart>:** Well, I hesitate to add that this is, again, a single arm study. It's multi-institutional, but it's single arm, open label, although the x-rays get measured not only by the radiologist at the study sights, they get measured by an independent masked radiologist who has no knowledge of the patient's treatment or other issues. He just sees stones and measures target lesions. Obviously, my speculation is that if you get more drug in on a sustained basis and we know that we can do that. TOCOSOL Paclitaxel is very well tolerated and most doses are delivered on time at full dose. And, I think that that may go a long way toward explaining why we are seeing a higher response rate. If you use another drug where because of toxicity, you have to back off on the dose, you skip a lot of doses, there is less chance for that drug to reach its maximum effectiveness.



**<Q – Vinny Jindal>:** Got it. And of that 51%, can you give us a breakdown of what are the PRs versus CRs?

**<A – Michael Martino>:** Oh dear. I don't — I'm afraid I don't remember. I — it's early on. And, most of them are PRs, obviously. But, it's early on and I don't have the numbers in front of me. I think that the real issue was we wanted to get out some information for you guys today so you know where we are heading. But, it's not uncommon that best responses what we will eventually be talking about, rather than the current level of the case ones that we have in house. As I mentioned, they are incomplete. We don't have all of the data in on all of the patients.

**<Q – Vinny Jindal>:** Got it. Thanks, guys.

**<A>:** Sure.

**<A – Michael Martino>:** Thanks, Vinny.

Operator: Your next question comes from Alan Long.

**<Q – Alan Long>:** Hi, everyone.

**<A – Michael Martino>:** Hi, Alan.

**<Q – Alan Long>:** Can you tell us which disease indication the Phase III is targeted at and if you can't yet be specific, can you provide us some color in your thinking with regards to choosing the pivotal indication?

**<A – Michael Martino>:** Well what we have said is, that the lead indication will be one in which Taxol is approved as a single-agent therapy so that pretty much says that it's second-line metastatic breast or second-line ovarian. And, there are a variety of factors that we have considered in the decision including regulatory factors, clinical factors, and commercial factors. Clearly, we have made a proposal to FDA and as Michael indicated, we are in the process of iterating our communications on that. We believe that we have a very clear path forward and we will look forward to discussing the specifics of the study once we have that final SPA.

**<Q – Alan Long>:** For your Phase IIb trial on breast cancer, might you be releasing some interim data-like progression before December, and if so, through what venue?

**<A – Michael Stewart>:** Well, it's hard to predict when data will be available of course, and I don't want to speculate on that. I will say that our philosophy and indeed our policy has been to release data at scientific meetings such as ASCO or in the absence of that, to provide material updates on our quarterly calls. And that will continue to be our policy and our practice.

**<Q – Alan Long>:** One more question. Can you provide some color at this time of what you are looking for in a partner?

**<A – Michael Martino>:** Well, we are looking for someone who is committed to oncology. We are looking to someone who is committed to the vision of TOCOSOL Paclitaxel as a Taxane of choice with a clear understanding of the requirements for the ongoing lifecycle management of the product that is inherent in our vision and we are looking for someone who can provide resources, of course money, but as importantly, clinical, regulatory, as well as, the commercial resources necessary to complete development and launch the product.

**<Q – Alan Long>:** You're not necessarily looking at just Big Pharma there?



**<A – Michael Martino>:** That is correct. I would continue to say that players at the table, potential partners, while they do include Big Pharma, also include companies that at least Wall Street would probably characterize as specialty pharmaceutical company.

**<Q – Alan Long>:** Thank you very much.

**<A – Michael Martino>:** Thank you, Alan.

Operator: Your next question comes from Mark Monane.

**<Q – Mark Monane>:** Hi, good afternoon. And, thanks for taking my question.

**<A – Michael Martino>:** Hi, Mark.

**<A>:** Hello, Mark.

**<Q – Mark Monane>:** A couple of questions here. In your press release, you nicely outlined why — what the limitations are of Taxol. Could you go over for us, how TOCOSOL potentially addresses those limitations, and therefore, talk about its potential in the real world?

**<A – Michael Martino>:** Sure. I'd like to hand it over to Michael to discuss that from a clinical perspective, and then, I'll give you the flavor of some primary market research that we've completed. Michael?

**<A – Michael Stewart>:** Well Mark, I think that the two broad categories are, one, the toxicities of the Cremophor/Ethanol formulation, whether it's Taxol or the generic equivalents, they have the same formulation. And, there are a number of toxicities that are associated with Cremophor. Neurotoxicity is certainly among the leaders there, but, there are cardiovascular toxicities as well, probably more vascular than cardiac. The other major area is the area of difficulty of use. Taxol injection has to be diluted, has to be done in a pharmacy, under a hood, an IVI mixture prepared, and that is labeled to be given over 3 hours. TOCOSOL Paclitaxel is a ready-to-use product. It is drawn into a syringe and given directly intravenously in 15 minutes. And so, I think that it's a very different kind of — you don't have to have a pharmacy. You don't have to have an infusion clinic. You don't have to have all the staff associated with that and most importantly, the patient doesn't have to sit there for 3 hours watching one drop after another go in.

**<Q – Mark Monane>:** That's fair.

**<A – Michael Martino>:** Now Mark, in terms of the primary market research, and this has been a pretty extensive study for us talking with not only oncologists, and in that category not only the thought leaders but the community practitioners, as well as, the pharmacists. And the results are consistent with previous surveys that we've completed although those previous surveys haven't been anywhere near as extensive or statistically rigorous as this one. And I think the topline results would say that, number one, efficacy remains the trump card in oncology. However, in this Taxane space, we believe that even if TOCOSOL Paclitaxel is approved as non-inferior to Taxol on objective response rate as the initial claim, if that is against a Taxol control arm response rate that is viewed as in line with the practitioner's previous experience with Taxol as well as the label and multiple published studies that that will be viewed as a strength of the product.

Secondly, regarding safety and tolerability, as Michael indicated the side effect that is at the top of the list for oncologists, and at the top of the list by a wide margin, is in fact peripheral neuropathy. And the reason is because there is simply no intervention available today to treat that condition save time. And what that means is that therapy has to be interrupted for the patient to try to recover from that side effect and, you know, unfortunately the tumor is also recovering from the effects of the drug.



**<Q – Mark Monane>:** Sure.

**<A>:** Finally, with those things in place we believe that our features and advantages on convenience and ease of use provide a solid platform for differentiations. Now if we are able in the design of our study to prove superiority over the long run in terms of timed progression and/or survival, again we believe that those will be very, very competitive claims to manage the life cycle of what would already be a competitive product.

**<Q – Mark Monane>:** All right, that's very helpful. I have a question that's an offshoot of your answer, and that is a little bit about the pharmacokinetics and the pharmacodynamics. We can get a very high level of Taxol, but that's not necessarily good because with extra efficacy one can get extra side effect profile. Can you talk about — without giving the results of the ASCO presentation, can you talk about those issues of release and leakiness and blood concentrations and how we should think about that in treating the cancer and preventing resistance.

**<A – Michael Stewart>:** Yes, I think the easiest way to go back to it is to look at what we've previously recorded and what we see coming out of the Phase IIa studies and now we're seeing the same thing out of the Phase IIb work in breast cancer, and that is when you give this drug on a weekly basis at the doses we're giving it, it is very well tolerated. People are able to get almost all of their intended therapy on time at full dose. They don't have to have it interrupted for toxicity. They don't have to have it delayed. They don't have to have dose reductions for the most part, and I think that that's the critical issue. You know, we're able to get more in; we're able to get it in on a sustained consistent basis. That's the key to efficacy and it's being done without toxicity that requires interruption or dose reduction.

**<Q – Mark Monane>:** It's important. Got it. And the last question has to do with the CMC. You highlight it nicely in your press release, but can you talk about some of the issues, addresses. We know in biotechnology CMC issues are becoming more and more important. I think they were always there but it seems to be more and more important. How — what should we get — what should we understand after a meeting from the FDA in your ability to moving forward into the Phase III trials?

**<A>:** Well I think the major take-away from that is that we have a stable product that is well characterized, validated as scale that is suitable to support launch, and with a process that is reliable, repeatable, and predictable, i.e. all the good code words that exist to ensure GMP manufacturer of product. More simply, we have a manufacturable product, and we feel good about that progress.

**<Q – Mark Monane>:** Terrific. Thanks for the added information. Appreciate it.

**<A>:** Thank you Mark.

**<A>:** Thanks Mark.

Operator: Your next question is a follow-up question from Matt Kaplan.

**<Q – Matthew Kaplan>:** Hi, just a quick follow-up question from — on Mark's. Focusing on — a little bit on the neurotoxicity, if you look at the toxicity profile of potentially two of your competitors, one that's on the market and one that's not there, specifically Abraxene on a weekly basis, they had a 10% rate of Grade 3 neuropathy, and Xyotax had a rate of neuropathy in the 30 — occurrence in the 30% to 50% range, and a Grade 3 of 4% to 19%. How does your — obviously you only have weekly data, but how does yours stack up to those competitive products, which look like they have higher rates of neuropathy than Taxol perhaps?

**<A – Michael Stewart>:** Higher rates of neuropathy than Taxol on a weekly basis. I don't think so because —

**<Q – Matthew Kaplan>:** No, no, no. Those products look like they have a higher rate of neuropathy than Taxol. How does yours stack up?

**<A – Michael Stewart>:** Well, as we previously reported, we've got a 9% incidence of Grade 3 neuropathy and no Grade 4 neuropathy and that's on patients who have been on treatment for a year, up in one case, up to two years. The reason I was questioning you is because the Taxol data that Andy Seidman reported last year for weekly Taxol showed in all the — when they looked at all patients. There was a 23% incidence of Grade 3 peripheral neuropathy. When they looked at those patients who were dosed starting at 80 milligram per square meter or less, there was still a 19% incidence of Grade 3 peripheral neuropathy. So I think we're seeing neuropathy rates that are favorable compared to what's been reported for Taxol.

**<A – Michael Martino>:** We would conjecture, based on the data that one of the features, advantages, and benefits of this product is going to be a favorable neuropathy profile. Now, obviously, that is one of the points that will have to be proven holistically in our total integrated safety database of all the studies and specifically, we'll get our first head-to-head view of that, at least versus Taxol, in the Phase III study.

**<Q – Matthew Kaplan>:** Okay, thank you. That's all.

**<A>:** Thanks, Matt.

**<A>:** Thanks, Matt.

Operator: Your next question is a follow-up from Vinny Jindal.

**<Q – Vinny Jindal>:** Hey guys just had a quick question for you. In order to be able to reference the data that you guys produced for median survival in the ovarian, non-small cell, and bladder trials, in the Phase IIs, Michael Stewart, what generally are the median survivals you expect for those patient populations receiving either Taxol or another therapy, standard of care?

**<A – Michael Stewart>:** Well, and that why I mentioned when I said that the trials we're doing are single-agent TOCOSOL Paclitaxel and I think if you look at second-line populations, whether it's ovarian or lung or bladder, they tend to be treated with combination chemotherapies and you're seeing — and they range, depending on the size of the study, and there are several review articles that have listed a number of ways but what we're seeing for ovarian in terms of a survival duration of 74 weeks, what it is 16, 17 week, so it was 16, 17 months something like that, is certainly consistent with what's been reported for combination therapies, which is usually another platinum plus or minus something else. May include Taxane. Taxane plus platinum is sometimes used as second-line therapy in ovarian in patients who do not have primary resistance and 18 to 22 — 24 months is certainly reasonable for combination therapy. In non-small cell lung, is seven or eight months survival with combination therapy for second-line is thought to be very good and we're seeing this similar thing with single agent and again with bladder. If you get a 13 or 14-month survival, that's really where the numbers have been in this kind of locally, advanced, inoperable, or metastatic disease. So what we're seeing with single agent, I think, is certainly consistent with what's been published for combination regiments and second-line treatment of patients with those diseases.

**<Q – Vinny Jindal>:** Great. Thanks, Michael.

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



**Michael A. Martino, President, Chief Executive Officer and Director**

Yes, Michael, thank you. If there are no further questions, we'd like to thank all of you for joining us today. As Michael indicated earlier, we will be presenting the results of our clinical pharmacology study in a poster presentation at ASCO on the morning of May 15th. That's a Sunday, 8:00 AM, and we would hope to see you there. Our next opportunity to speak formally with you will be at our annual shareholders meeting on May 23rd in Belleview, Washington. In addition, we'll be presenting at the Needham & Company Annual Biotechnology Conference on May 26th in New York City. Both the annual meeting and our presentation at the Needham Conference will be broadcast live and archived on our website at www.sonuspharma.com. As always, we appreciate your continued support. We look forward to sharing our progress with you in the months ahead. Thank you, Michael. That concludes the call.

Operator: This concludes today's Sonus Pharmaceuticals First Quarter Conference Call. You may now disconnect.