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) **August 8, 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 August 8, 2005, Sonus Pharmaceuticals, Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 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 August 8, 2005, issued by Sonus Pharmaceuticals, Inc.

Exhibit 99.2 Transcript of Sonus Pharmaceuticals, Inc. second 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: August 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 August 8, 2005, issued by Sonus Pharmaceuticals, Inc.
Exhibit 99.2	Transcript of Sonus Pharmaceuticals, Inc. second quarter 2005 conference call.

NEWS RELEASE

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

SONUS PHARMACEUTICALS UPDATES CORPORATE PROGRESS AND REPORTS SECOND QUARTER FINANCIAL RESULTS

Company continuing to advance TOCOSOL® Paclitaxel toward Phase 3 testing

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

BOTHELL, Washington, August 8, 2005—Sonus Pharmaceuticals, Inc. (NASDAQ:SNUS) today reported financial results for the second quarter ended June 30, 2005 and updated its progress on 2005 strategic objectives, including the clinical and regulatory development of TOCOSOL® Paclitaxel, the Company's lead oncology candidate.

"We were very pleased to have met one of our key objectives during the second quarter by reaching agreement with the FDA on the Special Protocol Assessment (SPA) for the Phase 3 trial of TOCOSOL Paclitaxel," said Michael A. Martino, President and CEO of Sonus. "We are continuing to make excellent progress with TOCOSOL Paclitaxel, and in particular to move the product into Phase 3 testing this year. Completing the SPA was one critical step in that process as well as a key milestone for Sonus."

Second Quarter 2005 Highlights:

- Completed Special Protocol Assessment (SPA) process with the U.S. Food and Drug Administration (FDA) for the pivotal Phase 3 trial of TOCOSOL Paclitaxel. The FDA has agreed that the planned head-to-head comparison of TOCOSOL Paclitaxel and Taxol® will be appropriate, if properly conducted and analyzed, for Sonus to submit a 505(b)(2) New Drug Application based on a single pivotal Phase 3 trial. The study population will include women with metastatic breast cancer, and patients will be receiving paclitaxel as first- or second-line treatment for their disease. Approximately 800 evaluable patients will be enrolled in the study.
- Presented data from clinical pharmacology trial of TOCOSOL Paclitaxel at the American Society of Clinical Oncology (ASCO) annual meeting. Results from the study showed that TOCOSOL Paclitaxel delivers almost twice the exposure to paclitaxel that is delivered by

More...

Taxol. The Company believes that the ability to provide higher exposure to paclitaxel may lead to better anti-tumor activity, which will need to be validated in the Phase 3 study of TOCOSOL Paclitaxel.

- Submitted an abstract on Phase 2b study of TOCOSOL Paclitaxel in metastatic breast cancer to the San Antonio Breast Cancer Symposium that will be held in early December. As of the end of July 2005, results reported by the investigators indicate an objective anti-tumor response rate of 53% in the breast cancer study population, including at least one complete response (no radiographic evidence of remaining tumor).

Second Quarter Financial Results

For the second quarter of 2005, the Company reported a net loss of $4.1 million, or $0.19 per share, compared with a net loss of $3.8 million, or $0.19 per share, for the second quarter of 2004. For the first six months of 2005, Sonus reported a net loss of $8.9 million, or $0.41 per share, compared with a net loss of $7.3 million, or $0.39 per share for the same period of 2004. The higher net loss for the year-to-date financial results primarily reflected an increased level of spending as the Company continues to execute the clinical and regulatory plans for TOCOSOL Paclitaxel. Cash and marketable securities totaled $11.4 million at June 30, 2005.

Conference Call Information

The second quarter conference call will be web cast live on August 8, 2005 at 1:30 Pacific Time/4:30 P.M. Eastern Time and can be accessed at www.sonuspharma.com/events.html. An archive of the call will be available through the same link. A telephone replay will be available from August 8, 4:30 P.M. Pacific Time/7:30 P.M. Eastern Time, for one week at (800) 642-1687 or (706) 645-9291 for international calls; Conference ID 7868773.

About TOCOSOL Paclitaxel

TOCOSOL Paclitaxel is a novel, proprietary formulation of the leading 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 of the products prior to administration. TOCOSOL Paclitaxel has generated encouraging data on safety and anti-tumor activity in Phase 2 trials in breast, ovarian, non-small cell lung and bladder cancers.

About Sonus Pharmaceuticals, Inc.

Headquartered near Seattle, Washington, Sonus Pharmaceuticals, Inc. is focused on the development of therapeutic drugs that may offer improved administration, safety, tolerability and effectiveness for the treatment of cancer and related conditions. For additional information on Sonus, including 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 the Phase 3 clinical trial 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 and Form 10-Qs for the first two quarters of 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 the Phase 3 clinical trial 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	2,869	2,660	5,992	5,228
General and administrative	1,296	1,157	3,039	2,203
Total operating expenses	4,165	3,817	9,031	7,431
Operating loss	(4,165)	(3,817)	(9,031)	(7,431)
Other income, net	74	55	165	91
Loss before income taxes	(4,091)	(3,762)	(8,866)	(7,340)
Income taxes	—	—	—	—
Net loss	$ (4,091)	$ (3,762)	$ (8,866)	$ (7,340)
Net loss per share:				
Basic	$ (0.19)	$ (0.19)	$ (0.41)	$ (0.39)
Diluted	$ (0.19)	$ (0.19)	$ (0.41)	$ (0.39)
Shares used in calculation:				
Basic	21,377	19,970	21,365	19,008
Diluted	21,377	19,970	21,365	19,008

Condensed Balance Sheets
(in thousands)

	June 30, 2005 (unaudited)	December 31, 2004
Assets:		
Cash and marketable securities	$ 11,377	$ 20,580
Other current assets	185	459
Property and equipment, net	1,238	1,480
Other assets	52	52
Total assets	$ 12,852	$ 22,571
Liabilities and stockholders' equity:		
Accounts payable and accrued expenses	2,260	3,177
Lease obligations	55	121
Deferred rent	164	196
Stockholders' equity	10,373	19,077
Total liabilities and stockholders' equity	$ 12,852	$ 22,571

raw transcript :callstreet

Sonus Pharmaceuticals Inc	SNUS	Q2 2005 Earnings Call	Aug. 8, 2005
Company•	*Ticker•*	*Event Type•*	*Date•*

• MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon. My name is Natasha and I will be your conference facilitator today. At this time, I would like to welcome everyone to the Second Quarter 2005 Conference Call. [Operator Instructions] I would now like to turn the conference all over to Miss Pamela Dull, Director of Investor Relations. Ma'am, you may begin your conference.

Pamela Dull, Director of Investor Relations

Thank you Natasha and good afternoon everyone. Welcome to Sonus Pharmaceuticals Second Quarter Conference Call. Again, I am Pamela Dull, Director of Investor Relations. To begin the call, I would 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, our Form 10-Qs for the first two quarters of this year and other SEC filings, all of which can be accessed on our website. I will now turn the call over to Mike Martino, President and Chief Executive Officer of Sonus.

Michael Martino, President, Chief Executive Officer

Thanks, Pam. Hello everyone and thank you for joining us. On the call with Pam and me today are Alan Fuhrman, our Chief Financial Officer; and Dr. Michael Stewart, our Chief Medical Officer. We will use the following approach for today's call. First, I will update our progress in corporate partnering discussions. Michael Stewart will then provide a review of our clinical and regulatory activities for TOCOSOL Paclitaxel. Next, Alan will provide a brief summary of our financial results and finally, we will be happy to answer any questions you may have.

So, let's get started with an update on our corporate partnering discussions. We have consistently said that our objective is to maximize the value of TOCOSOL Paclitaxel through a corporate partnership or partnerships. We have also said that we expected the ongoing strength and durability of our clinical data, the validation of our regulatory strategy, and competitive dynamics to converge this year to put us in a better position to achieve that objective. At this point, we are in the process of negotiating in parallel with several different prospective partners. A number of these discussions have advanced to late stage negotiations of terms.

Competitive proposals in hand offer various combinations of clinical, regulatory, and commercial expertise, financial terms, and geographic reach. As our negotiations progress, we are assessing and balancing the trade-offs between capabilities, financial terms, and time lines to get to a working collaboration. It is difficult to speculate on when this process will be completed. However, you will hear shortly from Michael that we are on track with start-up activities to begin patient enrollment by the end of September. You will then hear from Alan that we will need to strengthen our balance sheet to be in a position to do that. Let me say simply that we continue to believe that we will execute our strategy and will be in a position to implement the Phase III trial on schedule.

As I said earlier, one of the catalysts that has provided further impetus to these partnering discussions has been the validation of our regulatory strategy. This validation was achieved with the completion of the Special Protocol Assessment, or SPA, for the pivotal Phase III trial of TOCOSOL Paclitaxel, which we were very pleased to announce a few weeks ago. I will now turn

the call over to Michael to update you on our ongoing clinical experience with TOCOSOL Paclitaxel as well as the details of the planned Phase III trial.

Michael Stewart, Chief Medical Officer

Thanks very much, Mike. We continued to make excellent progress with the development of TOCOSOL Paclitaxel during the second quarter. The full results of the clinical pharmacology trial that compared TOCOSOL Paclitaxel to Taxol were presented at ASCO in mid-May by Professor Axel Hanauske, the leading enroller in the study, and they were received with high interest on the part of many oncologists who attended the meeting. In short, TOCOSOL Paclitaxel delivers almost twice the exposure to Paclitaxel on a dose-for-dose basis that Taxol delivers.

What that means is that a weekly dose of TOCOSOL Paclitaxel at 100 mg per square meter, which has been shown in our Phase II trials to be very well tolerated over extended treatment periods gives as much Paclitaxel exposure per dose as the standard dose of Taxol that is given every three weeks. Taxol at the pharmacologically equivalent dose of 175 mg per square meter is given every three weeks because it cannot be tolerated if given more often at that dose. It may well be that one reason we have seen the impressive efficacy results that were shown in the Phase II studies of TOCOSOL Paclitaxel is that patients' tumors are getting exposed to greater amounts of the anti-cancer drug on a regular, sustained basis. At the same time, the tolerability of being able to take it on a weekly treatment program has also been demonstrated. All together the results suggest that TOCOSOL Paclitaxel truly may be a better Taxane product. We believe we're seeing much the same thing in our ongoing Phase IIb study in metastatic breast cancer. The confirmed objective response rate reported by the study investigators as of the end of July is 53%, including at least one complete response, and that has a 95% Confidence Interval of 38% to 68%. Independent radiology review will be completed this month. We also expect to have the data to estimate median time-to-progression by the end of the summer. We submitted an abstract about this study to the San Antonio Breast Cancer Symposium that will be held in early December with the intention of providing a full update on the study at that time.

Turning now to the upcoming Phase III pivotal registrational trial that will compare TOCOSOL Paclitaxel to Taxol. As Mike mentioned, we completed the Special Protocol Assessment process with the U.S. FDA at the end of June. We believe that was a valuable investment of time as it typically reduces the NDA review period compared to the time the FDA usually takes for NDAs submitted without a Special Protocol Assessment.

The FDA has agreed that the planned head-to-head comparison of TOCOSOL Paclitaxel and Taxol will be appropriate if properly conducted and analyzed for Sonus to submit in a New Drug Application that is based on that single pivotal trial. The study population will be women with metastatic breast cancer. Both drugs will be administered to patients on a weekly dosing schedule. We expect to enroll 800 evaluable patients with equal numbers of patients randomly assigned to TOCOSOL Paclitaxel or Taxol. Patients will be receiving Paclitaxel as first or second line treatment for their breast cancer.

The primary end point is objective response rate, which is the sum of confirmed partial and complete response rates. Secondary end points are progression-free survival duration and overall survival duration. The primary statistical analysis will be for non-inferiority on objective response rate, and if that analysis is statistically

significant, the data will be analyzed for superiority of TOCOSOL Paclitaxel over Taxol. As is standard practice for pivotal trials, study progress and interim assessment for safety and efficacy results will be monitored by an independent Data Monitoring Committee who will meet periodically to determine if there are any significant safety issues and whether the study should continue to its planned conclusion.

The initial New Drug Application for TOCOSOL Paclitaxel will be submitted on the basis of the analyses on objective response rate. The FDA has collaborated interactively with us during the last several months to establish the study end points and the critical definitions of the statistical analyses that would lead to NDA approval. Approval must, of course, be based on results showing the relative value of TOCOSOL Paclitaxel over Taxol. The basis for the 505(b)(2) approval could be demonstration of superiority of TOCOSOL Paclitaxel over weekly Taxol if the data show that, or demonstration of non-inferiority of TOCOSOL Paclitaxel to weekly Taxol in the context of either an updated Taxol label that includes the weekly dosing regimen, which the FDA is currently pursuing, or of clinical data from comparisons of weekly Taxol versus the currently approved 3-weekly regimen. We expect that the NDA review period will be about a year, and commercial launch would occur promptly if marketing approval is granted. Meanwhile, the study will actually continue for an estimated two additional years or so until median overall survival duration has been determined.

In parallel with completing that SPA agreement in June, we also began start up activities for the Phase III trial. Identification of and contracting with investigators and submissions of regulatory dossiers for review by health authorities have been underway in multiple countries. We expect to activate up to 150 study sites in North America, the European Union, Eastern Europe, Israel and South Africa. Based on available financial resources, our goal is to begin activating sites and enrolling patients by the end of September, and we would expect to have all sites up and running by the end of the year. We anticipate that patient enrollment in the study will be completed within six to nine months, depending primarily on the speed with which we are able to activate all study sites.

Based on the positive nature of the clinical data to date and feedback from oncologists who have used the product, we continue to believe that TOCOSOL Paclitaxel will be differentiated from other Taxane products on the market. TOCOSOL Paclitaxel appears to be very well tolerated when administered on a weekly basis at the doses that we're using.

Patients in our studies have been able to get almost all of their intended therapy on time at full dose, and they quickly resume full dose if a temporary dose reduction is needed. That's the critical issue. Getting more drug on a sustained, consistent basis may be the key to efficacy, and with TOCOSOL Paclitaxel, we may be able to do that without the dose-limiting toxicities that are common with other Taxane products.

In addition, our product is a convenient, ready-to-use formulation that does not require any special preparation. TOCOSOL Paclitaxel is given as a 15-minute infusion, which may eliminate the need for patients to receive their therapy in an infusion clinic or hospital.

We are truly optimistic about the opportunities for TOCOSOL Paclitaxel to become the preferred choice for people who need Taxane chemotherapy, and we're eager to initiate the Phase III trial to confirm its potential value.

Alan, I'll now turn the call over to you.

Alan Fuhrman, Senior Vice President and Chief Financial Officer

Thank you, Michael. Let me briefly review the financial results for the quarter, which we reported in our press release this afternoon.

For the second quarter of 2005, we reported a net loss of 4.1 million or 19 cents per share, compared with a net loss of 3.8 million or 19 cents per share for the second quarter of 2004. For the first six months of 2005, we reported a net loss of 8.9 million or 41 cents per share compared with a net loss of 7.3 million or 39 cents per share for the same period of 2004. The higher net loss

for the year-to-date financial results primarily reflected an increased level of spending as we continue to execute the clinical and regulatory plans for TOCOSOL Paclitaxel.

We ended the quarter with 11.4 million of cash and no long-term debt. As we've outlined in the past, we are seeking a partner to fund all, or a portion, of the Phase III trial for TOCOSOL Paclitaxel. We estimate that the cost of this Phase III trial will be in the $40 million range over a period of about 3 years or longer with 50% of the cost being incurred within 12 months of the initiation of patient enrollment. As we've previously indicated, we continue to expect that our base burn rate will be approximately 1.6 million per month, on average, for fiscal year 2005. Please note that this base burn rate does not include the cost of the Phase III trial for TOCOSOL Paclitaxel.

That completes the snapshot of our financial results, and I'd like to turn the call over to Mike.

Michael Martino, President, Chief Executive Officer

Thanks, Alan. We remain very focused on moving TOCOSOL Paclitaxel into Phase III testing. Our near-term goal is to complete a corporate partnership to secure the necessary financial resources to complete the development and ensure the successful commercialization of the product. While we still have a lot of work ahead of us, it's exciting to be moving closer to our ultimate goal of bringing the benefits of TOCOSOL Paclitaxel to cancer patients and physicians. Accordingly, I'd like to take this opportunity to thank the entire Sonus team for their hard work and dedication in reaching this point in the development of the product.

That completes our prepared remarks, and we'd be pleased to answer any questions. Natasha, could you please open the line for the first question?

- **QUESTION AND ANSWER SECTION**

Operator: Yes sir. [Operator Instructions] We will pause for just a moment to compile the Q&A roster. Your first question comes from David Miller with Biotech Monthly.

<Q – David Miller>: Hi, good afternoon. Thanks for taking my questions.

<A>: Hi David.

<Q – David Miller>: You mentioned in your introductory comments that you need to strengthen the balance sheet. Are you going to do that via the partner only, or are you contemplating, perhaps, doing some sort of a financing?

<A>: Oh, I would say our primary strategy is the partnership. I'm not going to speculate on other financing vehicles at this point.

<Q – David Miller>: So you have enough cash in the bank that you're not going to run into a situation where you can't close the deal before you run out of cash?

<A>: I don't think so.

<Q – David Miller>: Okay. How long would you expect this particular class of patients to achieve the objective response end point?

<A>: You mean how soon will they – will we start to see responses?

<Q – David Miller>: Yes.

<A>: Given that – this is just based on both the literature and what we've seen from our own results, the median time to response is 2 to 3 months. That is not the median time to best response. So we would expect to start seeing responses by the first time we look at the x-rays, which is 8 weeks after patients have been on therapy for 8 weeks. We look every 8 weeks, so we'll see responses at week 8, we'll see responses at week 16. Whenever a response is seen, it has to be confirmed by another x-ray that's taken 4 weeks later. So I would think it's very likely that we will probably identify all responders within 6 months of their starting treatment.

<Q – David Miller>: All right. So it takes a number of weeks after that to find out what their best response is as well as to get those independently confirmed.

<A>: Yes. Those things can go, yes, to a certain extent some of that goes on in parallel.

<Q – David Miller>: You mentioned that you're going to be enrolling both first- and second-line patients. Are you going to stratify those?

<A>: Yes.

<Q – David Miller>: Across the two arms?

<A>: Yes. The stratification, because this is under 505(b)(2), the indication has to be the same as is granted for Paclitaxel. You'll see that in the labels for all the generic Paclitaxel products, you'll also see it in the label for the albumin-bound product, and Taxol has not demonstrated success head to head against Anthracycline so we need to comply with the FDA requirements under 505(b)(2) and to stratify for prior Anthracycline therapy.

<Q – David Miller>: You talked about how it's going to take – I'm trying – there's a question I asked about the median time to response is I'm trying to back into when we might see – get some answer on the objective response. If you're going to start in September, it's going to take you, call it 9 months to enroll, that puts it in – that puts us into middle of next year before the patients are all enrolled. Are we looking at seeing data by the end of 2006 or is that too optimistic?

<A>: I don't think it's unduly optimistic at all. I am sure that the data will exist; the issue is the trial is being monitored by an independent Data Monitoring Committee. They're going to meet about quarterly to review all of the results, and we won't know what the results are until they tell us they've reached a conclusion.

<Q – David Miller>: Okay. And is this conclusion done by a trigger point by a certain number of events or how does it work?

<A>: Given that we're actually, as I said, the enrollment we're anticipating is 6 to 9 months, we actually think it's going to be on the short end of that, and given that the enrollment will occur very rapidly, there's not an interim, planned interim analysis that would stop the trial. So I think it's very likely that all of the data will become mature within a few month period.

<Q – David Miller>: Okay. So what's the trigger point for actually unblinding it?

<A>: When – that will be when the study's concluded. When they have responses, information on all of the patients.

<Q – David Miller>: On all patients, okay.

<A>: Because the challenge we have is the trial needs to continue for survival endpoint.

<Q – David Miller>: Right.

<A>: So there's an independent statistician who will be preparing analyses for the DMC. The DMC will be looking at it – they're primarily going to be looking at it for safety but they will see efficacy. They will probably see that in a blinded fashion, treatment A versus treatment B, and then when they tell us that we reached a statistically valid answer that's when we'll know.

<Q – David Miller>: Are there any other stratifications?

<A>: No.

<Q – David Miller>: Okay, great. Thank you very much and I commend you on releasing this much detail on the study. It's a refreshing change from some of the companies we cover.

<A>: Thank you David. Operator: Your next question comes from Vinny Jindal with Wedbush Morgan Securities.

<Q>: Hey guys. Thanks for taking my call.

<A>: Hi Vinny.

<Q>: I was wondering Michael Stewart, you talked about this trial's going to have as its comparator arm weekly Taxol, is that right?

<A>: Correct.

<Q>: And that's not currently in the label. I'm wondering how – what kind of dynamics that might introduce since through the 505(b)(2) route that that involves referencing a label for an already approved drug.

<A>: Right. And that certainly is the topic, the gist of several discussions we've had with FDA. I think the important thing to notice is that this is the study design that the FDA has approved and they don't think this is going to be a problem and neither do we.

<Q>: It's fair enough. It's their game to call. Regarding the start of the trial, you guys have given guidance that you're going to have your first site up and running and the trial initiated by the end of the third quarter, how much lead time do you need? I know you guys have already done a lot of the leg work already, before, though, you start that trial to have a partner on board to make sure that their ideas for the trial dovetails with yours even though you've been keeping them updated now. I'm sure that dynamic changes when the partner's on board, so how much time before that actually, like end of September drop dead date do you expect to have the partner on board or I think need to?

<A>: I think that train on the pivotal trial has left the station and we've been very clear with potential partners on that. I would anticipate that we will have a joint development committee that will be overseeing the progress of the trial. But given that we have an SPA, given that we've submitted regulatory dossiers, given that we're going to be going in front of IRBs, there's very little that could be done to save that trial, save amendments, which are time consuming, costly and frankly, we think that we propped through those issues with plenty of input from lots of people including potential partners as they've commented along the way. The important aspect of it, I think, will be the involvement of the partners and the discussion of life cycle management strategy. I think as we have, perhaps, inferred several times along the way, we now have a number of other trials in the can, so to speak, with protocols either specified or at least sketched out of additional trials that we'd like to do to have results available to support commercial launch. And I think that the partner will have a great deal of say in those trials including which ones will get done and on what time schedule and which ones won't get done.

<A – Michael Stewart>: Vinny, this is Mike Stewart. I would just add that we have not been doing this in isolation obviously as we've had negotiations with our potential partners. Those have involved a great deal of back and forth with their clinical and regulatory groups and I think that we share common thinking on all of this. It's part of the process we've been going through to try to figure out about them and them to figure out about us.

<Q>: Got it, that's great. Michael Stewart, let me ask that 53% metastatic breast cancer response rate that you mentioned.

<A – Michael Stewart>: Right.

<Q>: Is that the radiographic response rate or is that investigator reported?

<A – Michael Stewart>: It is radiographic reported by the investigator institutions. So these are the institutional radiologists. What happens is that every target lesion when the patient is enrolled is recorded on the case form and then at every observation point, the measurements reported by the institutional radiologists are noted on the case report form. Those data come in and are tabulated internally here to determine the level of response. In addition, the films have now gone to an independent radiologist, and I'm expecting final confirmation from that radiologist by the middle of this month.

<Q>: Okay. And if there's any movement on that percentage, that'll be announced in a press release?

<A – Michael Stewart>: Well that would only be if – the independent radiologist, of course, doesn't have access to all the rest of the patients' records. They just measure film. But there's always some gap between the overall response that is – that comes from the investigator who's taking total care of the patient and the independent radiologist who sees only the film and doesn't see the non-imaged lesion. But yes, that 53% is not going to go down. We already have those data on case report forms.

<Q>: Got it.

<A – Michael Stewart>: Which is what the independent radiologist would come up with. That was for measurements responses noted by week 16, confirmed by week 20. I would point out that the concordance between the independent radiologist and the investigators for week 8 responses, confirmed at week 12, was 80%. Which is very high actually.

<Q>: And that was week 15 in the week 20? Or week 16

<A – Michael Stewart>: That was weeks 8 and 12. This is now week 16 and 20.

<Q>: Week 16 and 20. Right. Okay and then any indication about safety data on that trial? Are we going to have to wait for San Antonio Breast for that or are you going to give any indication of neutropenia or neuropathy, any of those kind of major

<A – Michael Stewart>: I can tell you thus far, because you know data is still cranking in, but thus far, everything we're seeing is entirely consistent with what we've seen in other trials. When I look at grade 3, 4 numbers, they're just lining up just like they have for the other study.

<Q>: Okay. Thanks for answering my questions guys.

<A>: Thank you Vinny. Operator: Your next question comes from Matt Kaplan with Punk, Ziegel & Company.

<Q – Matt Kaplan>: Hi guys. Thanks for taking my question.

<A>: Hi Matt.

<A>: Hello Matt.

<Q – Matt Kaplan>: Sorry I jumped on the call a little later, and I guess a question for Alan if he could give us – or Mike, Mike Martino, if you could give us some sense in terms of the budget for the second half of '05 and also 2006, what you're thinking in terms of where the burn rate is heading in the coming months?

<A – Michael Martino>: Oh, listen, Alan doesn't get many questions. I'm not going to steal that one from him.

<A – Alan Fuhrman>: Thanks Matt. What we had said is we continue to see our base burn rate, which will not include the Phase III pivotal trial, through the balance of the year. Turn outs for the average for the year is 1.6 million per month, on average. And then we still believe that the trial is going to be around $40 million and that, from the start of patient enrollment, through the first full year of the study after that, we'll spend roughly half of the $40 million that we're projecting. So I think that gives you a pretty good guide of where we think the balance of the year will come in spending-wise.

<Q – Matt Kaplan>: Great. Thank you. I think most of my other questions have been answered.

<A>: Thanks Matt.

Operator: [Operator Instructions] At this time, there are no further questions. Are there any closing remarks?

MIke Martino, President, Chief Executive Officer

There are. Thank you Natasha. I'd like to mention that our next opportunity to speak to you will be at two major investor conferences in September, including the Roth Capital Partners conference, which is being held September 7 and 8 in New York City, and the ThinkEquity Partners growth conference scheduled for September 12 through 15 in San Francisco. These presentations will be broadcast live and archived on our website.

So to wrap, as always we appreciate your continued support and interest. That concludes our call for today and we thank you for your participation.

Operator: This is today's Second Quarter 2005 Conference Call. You may now disconnect.