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) **March 15, 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 1.02 Termination of a Material Definitive Agreement.

On March 15, 2004, Sonus Pharmaceuticals, Inc. issued a press release indicating that on March 15, 2005, Sonus delivered an irrevocable notice to the Chief Executive Officer of Synt:em, S.A., a privately held French Company, pursuant to Sections 8.1(e) and 8.2 the Amended and Restated Stock Purchase Agreement dated December 22, 2004 by and among Sonus and the stockholders of Synt:em S.A., ("Agreement"), that Sonus is terminating the Agreement effective March 31, 2005. A copy of the press release is attached as Exhibit 99.1.

The Agreement contemplates that the acquisition of Synt:em, S.A. by Sonus would close on or before March 31, 2005. The Agreement further provides that if the transaction does not close by that date, the Agreement can be terminated at the discretion of either party. Management of Sonus has concluded that despite the best efforts of the parties to complete the transaction, it is impossible to consummate the transaction by March 31, 2005.

In reaching its conclusion to terminate the Agreement, management weighed the increased human and financial resources required to take advantage of opportunities with TOCOSOL® Paclitaxel, Sonus' lead oncology candidate, against the human and financial resources required to complete the transaction and subsequent integration of the Synt:em S.A. business with Sonus. Management concluded that the best course of action was to focus its resources on opportunities with TOCOSOL® Paclitaxel and remain as a standalone company.

According to the terms of the Agreement, properly terminating the Agreement pursuant to Section 8.1(e) will not result in any material early termination penalties or financial liability to Sonus.

Item 2.02 Results of Operations and Financial Condition.

On March 15, 2005, Sonus issued a press release to report certain strategic accomplishments in 2004. The press release is furnished as Exhibit 99.2 and is incorporated herein by reference.

In addition, on March 15, 2005, Sonus held a conference call with analysts and investors, the transcript of which is furnished as Exhibit 99.3 and is incorporated herein by reference.

The press release and conference call transcript contain forward-looking statements regarding Sonus and include cautionary statements identifying important factors that could cause actual results to differ materially from those anticipated. The information in this Current Report on Form 8-K, including Exhibits 99.2 and 99.3, is furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Exhibits.

Exhibit 99.1	Press Release of Sonus Pharmaceuticals, Inc. issued on March 15, 2005 entitled "Sonus Pharmaceuticals Terminates Proposed Acquisition of Synt:em".
Exhibit 99.2	Press Release of Sonus Pharmaceuticals, Inc. issued on March 15, 2005 entitled "Sonus Pharmaceuticals Highlights Progress in 2004".
Exhibit 99.3	Transcript of Sonus Pharmaceuticals, Inc. conference call held on March 15, 2005.

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: March 16, 2005

By: /s/ Alan Fuhrman

Alan Fuhrman
Senior Vice President and Chief Financial Officer

EXHIBIT INDEX

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Exhibit 99.3	Transcript of Sonus Pharmaceuticals, Inc. conference call held on March 15, 2005.

NEWS RELEASE

CONTACT: Pamela L. Dull, Sonus Pharmaceuticals, Inc., (425) 487-9500, Ext. 255
MEDIA CONTACT: Sheryl Seapy, EVC Group, (415) 272-3323; sseapy@evcgroup.com

Sonus Pharmaceuticals Terminates Proposed Acquisition of Synt:em

BOTHELL, WA—March 15, 2005—Sonus Pharmaceuticals, Inc. (Nasdaq:SNUS) today announced that it had notified Synt:em, S.A. of the Company's decision to terminate the proposed acquisition of Synt:em, effective March 31, 2005, the termination date under the transaction agreement.

"In reaching this strategic decision, we considered the strength of the opportunities in front of us with TOCOSOL® Paclitaxel, our lead oncology candidate, as well as the human and financial resources required to take advantage of those opportunities," said Michael A. Martino, President and CEO of Sonus Pharmaceuticals. "We concluded that the required focus of our resources is best achieved as a stand-alone company at this time. We continue to have high regard for the management, pipeline and technology of Synt:em, and we wish them continued success."

Conference Call Information

Sonus management will be available to answer questions on the termination of the Synt:em acquisition during its year-end 2004 conference call, which is being held today March 15, 2005, 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 replay of the conference call will also be available via telephone for one week at (800) 642-1687 or (706) 645-9291 for international calls; Pass code: 5280315.

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 therapies. The Company's lead product candidate is TOCOSOLÒ Paclitaxel, a new formulation of the widely prescribed anti-cancer drug paclitaxel. TOCOSOL Paclitaxel has been designed to overcome the limitations associated with TaxolÒ 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

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administration. Sonus is currently in discussions with the FDA to finalize the pivotal Phase 3 protocol for TOCOSOL Paclitaxel, which the Company believes will be initiated in 2005. For additional information, including news releases, please visit the Company's web site at 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. As discussed in Sonus Pharmaceuticals' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed on March 12, 2004 and Quarterly Report on Form 10-Q filed November 15, 2004, 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; risks that the Company will not be able to initiate Phase 3 trials for TOCOSOL Paclitaxel; such approvals are lengthy and expensive and may never occur; 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; 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; and risks of successful development of additional drug delivery products. Sonus 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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sonus pharmaceuticals

NEWS RELEASE

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

SONUS PHARMACEUTICALS HIGHLIGHTS PROGRESS IN 2004

Company focused on moving lead cancer product into Phase 3 clinical trials

Year-end conference call to be held today at 1:30 P.M. Pacific Time

BOTHELL, WA—March 15, 2005—Sonus Pharmaceuticals, Inc. (Nasdaq:SNUS) today reviewed its progress and key achievements in 2004.

"During 2004, TOCOSOL® Paclitaxel, our lead cancer product candidate, made steady, continuous clinical and regulatory progress," said Michael A. Martino, President and CEO of Sonus Pharmaceuticals. "We met a number of key milestones throughout the past year that advanced our goal of creating a more valuable company based first and foremost on maximizing our opportunities for TOCOSOL Paclitaxel. With plans to move TOCOSOL Paclitaxel into pivotal Phase 3 testing this year, our focus remains on developing and realizing the product's potential value as well as expanding and applying our technology to additional oncology candidates."

2004 Achievements

- Completed a clinical pharmacology study comparing TOCOSOL Paclitaxel and TaxolÒ to support the Company's primary 505(b)(2) regulatory strategy. The study has been accepted for presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting, being held May 13-17 in Orlando, Florida.
- Made three presentations on TOCOSOL Paclitaxel at the ASCO 2004 meeting, reporting encouraging Phase 2a data on safety and anti-tumor activity in patients with ovarian, non-small cell lung and bladder cancers.
- Initiated a Phase 2b breast cancer study of TOCOSOL Paclitaxel in September 2004, in which enrollment of 47 patients was completed in six weeks. Preliminary objective anti-tumor response data are in line with expectations.
- Met with the U.S. Food and Drug Administration (FDA) in December to discuss plans for Phase 3 testing and the content of the New Drug Application (NDA) for TOCOSOL Paclitaxel. The FDA indicated that it is appropriate for Sonus to pursue a single Phase 3 pivotal trial leading to submission of a NDA under a 505(b)(2) regulatory mechanism, which

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had been the Company's stated objective. The Agency and Sonus also agreed to use a Special Protocol Assessment process for the Phase 3 trial, which is an agreement with the FDA on the planned design, conduct and analysis of the study.

- Received Orphan Drug designation from the FDA for TOCOSOL Paclitaxel for the treatment of non-superficial urothelial cancer, of which the most common form is bladder cancer. This adds to the Fast Track designation granted by the FDA in 2003 for developing TOCOSOL Paclitaxel for the treatment of patients with metastatic or locally advanced, inoperable transitional cell carcinoma (TCC) of the urothelium. Sonus has a Phase 2b study of TOCOSOL Paclitaxel ongoing in advanced bladder cancer and is pursuing this indication in parallel with the 505(b)(2) program.
- Strengthened the intellectual property estate for TOCOSOL technology and TOCOSOL Paclitaxel with the issuance of four new patents, including two in the U.S., one in Taiwan and one in Canada. The Company was issued an additional U.S. patent in February 2005. Sonus now has a total of seven issued patents in the U.S. and two patents outside the U.S., with six of those specific to TOCOSOL Paclitaxel.
- Completed private equity financing that raised $14.4 million in net proceeds.

Conference Call Information

Sonus will highlight 2004 achievements and provide a company update during its year-end conference call today, March 15, 2005, at 1:30 P.M. PT/4:30 P.M. ET. The call will be web cast live and archived on the Company's web site at www.sonuspharma.com/events.html. A replay of the conference call will also be available via telephone for one week at (800) 642-1687 or (706) 645-9291 for international calls; Pass code: 5280315.

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corrected transcript

Sonus Pharmaceuticals	SNUS	Q4 2004 Earnings Call	Mar. 15, 2005
Company•	*Ticker•*	*Event Type•*	*Date•*

- **MANAGEMENT DISCUSSION SECTION**

Operator: Good afternoon, my name is Crystal and I will be your conference facilitator today. At this time I would like to welcome everyone to the Sonus Pharmaceuticals 2004 year-end conference call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer period. [Operator Instructions]. Ms. Pamela Dull, you may begin your conference.

Pamela Dull, Director of Investor Relations

Thank you Crystal and good afternoon everyone. Welcome to Sonus Pharmaceuticals' year-end 2004 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 the result of various risk factors, including those identified in our Form 10-K for the year ended December 31, 2003, our Form 10-Q for the quarter ended September 30, 2004, and other SEC filings, all of which can be accessed on our website. With that, I will turn the call over to Mike Martino, President and CEO of Sonus.

Michael A. Martino, President and Chief Executive Officer

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. We have a full agenda today and we are eager and excited to review our 2004 accomplishments and our key objectives for 2005. Before doing that, however, I'd like to say a few words about today's press release regarding Synt:em.

Our agreement with Synt:em contemplates that the transaction would close on or before March 31. The agreement further provides that if the transaction does not close by that date, then it can be terminated at the discretion of either party, without the payment of a termination fee or liability. Or, Sonus at its sole discretion can extend the effective date to April 30 by making a 500,000 euro forfeitable loan to Synt:em.

At this point, we have concluded that despite the best efforts of the parties, it will be impossible to consummate this transaction by March 31, based on SEC's review of the proxy, the resulting need for additional work to answer their questions, and the required minimum notice to our stockholders necessary to hold a special meeting to approve the transaction. Therefore, consistent with the provisions of the agreement and as indicated in our press release, we have informed Synt:em of our decision to terminate the stock purchase agreement effective March 31, 2005.

In reaching this difficult decision, the Board and I considered the opportunities we have in front of us with TOCOSOL Paclitaxel, as well as the human and financial resources required to take advantage of those opportunities. Specifically, we believe that TOCOSOL Paclitaxel has the potential to be a differentiated Taxane.

To achieve this goal, our clinical and regulatory team and advisors have recommended a pivotal Phase III trial with 700 evaluable patients. Because we believe such a trial is necessary to provide

the statistical rigor and power to achieve clinically relevant and meaningful primary and, importantly, secondary end-points to support a differentiated label for the product. Michael will go into a little more detail on this trial in his comments, but suffice it to say that this trial size is at the upper end of our previous guidance of between 400 and 800 patients.

We continue to believe that we will conclude a partnership to provide a significant portion of the resources necessary to undertake and complete this trial and I'll update our progress on those discussions later in the call. However, even with a partner the scope and cost of the Phase III trial, together with our desire to stay intimately involved with the ongoing development and commercialization of the product, simply requires us to maintain the focus of our existing resources, both human and financial, to assure the required progress.

And short-term, we believe, this progress on TOCOSOL Paclitaxel is essential to assure ongoing access to capital at an acceptable cost of capital and we believe this focus is best achieved as a standalone company. We continue to have very high regard for the management pipeline and technology of Synt:em and wish them nothing but continued success.

We remain committed to a longer-term vision of diversifying our business through external development efforts and expect that we will continue those efforts when we have achieved the near term objectives with TOCOSOL Paclitaxel that we will outline in this call. Now before proceeding with our 2004 business review and outlook for 2005, I'd like to ask Alan to provide a financial overview.

Alan Fuhrman, Senior Vice President and Chief Financial Officer

Thank you Mike. Regarding our 2004 financial results, with today's announcement on Synt:em we have requested a 15-day extension to file our 10-K in order to have adequate time to make the necessary changes to our 2004 financial statements and disclosures. We do not foresee any issue filing the 10-K within the extension period, and we will file a press release with our 2004 results as soon as practical. We did end 2004 with 20.6 million in cash. I also want to note that our Sarbanes-Oxley 404 audit is substantially completed and will be finalized when the 10-K is filed. I anticipate that our SOX 404 audit report will indicate that our internal control over financial reporting was effective as of December 31, 2004, which means that we did not have any material weaknesses in this process.

Next, I want to provide guidance for our 2005 burn rate. We expect to have a base burn rate of about 1.5 million per month during the first half of the year, increasing to approximately 1.6 million per month on average for the full year. The base burn rate does not include the costs of the Phase III pivotal trial for TOCOSOL Paclitaxel.

The 2005 expense for the trial will be determined when the special protocol assessment is finalized and the actual start date of the trial is known. We will provide additional guidance on the 2005 cost of the Phase III study once we have these additional details. Based on the size of the trial, as Mike has discussed, we estimate that the total cost of the trial over a period of about 3 years will be in the mid to upper $30 million range. At this point that completes our financial overview and I'll turn the call

back to Mike.

Michael A. Martino, President and Chief Executive Officer

Thanks, Alan. We'll use the following approach for the balance of our discussion today. First, I'll provide a high-level overview of our progress over the past year on development efforts with TOCOSOL Paclitaxel. And then Michael Stewart will provide some details on those accomplishments and bring us up-to-date with recent progress. Following Michael's update, I will

discuss our partnering efforts with TOCOSOL Paclitaxel, highlight achievements on our other key objectives for 2004, and summarize our objectives for 2005.

So let's begin and review 2004, which was a very busy and productive year for Sonus. We met a number of strategic objectives throughout the year that we believe enhance our ability to deliver greater value in 2005 and beyond. Our number one corporate goal for the year was to continue to develop and realize the value of TOCOSOL Paclitaxel. Appropriately, this goal consumed the lion's share of our attention and efforts during the year, and it accounts for a significant number of our accomplishments. Specifically, we made the following progress.

In March of last year, we completed patient enrollment in our clinical pharmacology study, comparing TOCOSOL Paclitaxel and Taxol. Treatment of the last patient to enroll was completed in June and the final data were available in September. The results enabled us to update the Phase III trial plan and submit our data and analysis to FDA in September in support of our 505b2 registrational strategy. An abstract reporting this study was also submitted to the American Society of Clinical Oncology in December, and I am very pleased to announce that the study has been accepted for presentation at the ASCO meeting this year, which is being held in Orlando, Florida May 13 to 17.

We were pleased to make three presentations about TOCOSOL Paclitaxel at the ASCO meeting in June 2004, reporting the results of our Phase IIa studies in ovarian, non-small cell lung, and bladder cancers. That was the first time that some U.S. and European investigators had seen detailed information about TOCOSOL Paclitaxel and a great deal of interest resulted from that exposure.

In September, we initiated a Phase IIb study of TOCOSOL Paclitaxel in the first line treatment of women with metastatic breast cancer. We were pleased that the study promptly enrolled 47 patients in about 6 weeks. We've had an early glimpse of the data from the study, which are in line with expectations, and Michael will share more about that with you in his update.

In September we also submitted a proposal to the FDA for our Phase III pivotal trial, supported by information from the clinical and non-clinical studies conducted to date with TOCOSOL Paclitaxel, including, as I said earlier, the data from the clinical pharmacology study. That submission led to a productive end of Phase II meeting with the FDA Oncology division in December, where they indicated that it would be appropriate to proceed with a single Phase III trial, leading to submission of a 505-b2 NDA for TOCOSOL Paclitaxel. Further, we agreed with FDA to use a special protocol assessment process ("SPA") for the Phase III study, which will result in an agreement with the agency about how the trial will be conducted and how the results will be analyzed. We believe that investing the time required for the SPA process before we activate the study is valuable for Sonus as it facilitates the review of the Phase III results and defines in advance what will be an acceptable basis for approval of our NDA.

In December, FDA granted orphan drug status to TOCOSOL Paclitaxel for the treatment of non-superficial urothelial cancer. We are pursuing an indication for the treatment of inoperable urothelial cancer in parallel with our 505b2 strategy. The orphan drug designation for this indication adds to the fast-track designation granted by FDA in 2003 for developing TOCOSOL Paclitaxel for the treatment of patients with metastatic, or locally advanced, inoperable urothelial cancer.

Finally, throughout the year our intellectual property estate for the TOCOSOL technology and TOCOSOL Paclitaxel was further strengthened with the issuance of four new patents, including two in the U.S. and one each in Taiwan and Canada, which are the first patents to issue outside the U.S. In the past couple of weeks, another U.S. patent on our technology has also issued. Sonus now has a total of seven issued patents in the U.S., and two non-U.S. patents, with six of those specific to TOCOSOL Paclitaxel. We believe that our intellectual property provides broad protection to practice in our space, and we are committed to expanding that protection for existing

products and potential new products. Now, before reviewing our progress on other key objectives for 2004, I'd like to turn the call over to Michael to provide more detail on our progress with TOCOSOL Paclitaxel.

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

Thanks very much, Mike. As mentioned earlier, we had an extremely productive end of Phase II meeting with the FDA Oncology Division late last year, during which we clarified several key issues about the pre-clinical, clinical and regulatory components that will be in our NDA when it is submitted. In particular, we discussed critical points about the design and conduct of our Phase III trial, and the content of this NDA. Based on the guidance that FDA provided, we submitted an updated protocol for review, and we are proceeding to finalize our agreements about the study design, how it will be conducted, and how the results will be analyzed. That is essentially what the SPA process is about, and it commonly takes about three to six months from start to finish. We have been extremely pleased with the timely responsiveness of the FDA thus far in the process, but clearly that is something we do not control. If we continue to make good progress, as we have done to date, we will be on track to initiate enrollment of patients into the Phase III study during the third quarter of this year.

Until the SPA is in place, we will not be sharing specifics about the Phase III study design. However, we can provide some general information. It is our intent to pursue a single pivotal trial, in an indication where Paclitaxel is approved as a single agent, with a primary end point of objective response rate, and secondary end points of time to progression and survival duration. We expect to submit the NDA with data on the primary end point, followed by supplemental applications when data are mature for the secondary end points. Most importantly, we intend that this trial will be powered to achieve statistical significance on all three end points. We may have to enroll up to 800 patients in order to do that. We believe this is the best strategy. It has the potential to competitively differentiate our product, and to increase its value to cancer patients and physicians. To support the NDA, we recently had a successful CMC meeting with the FDA to confirm the commercial manufacturing process, the product release specifications, and our stability testing program. Production of the clinical supplies needed for our trials will be performed this year, at the commercial scale.

Turning to the bladder cancer program, as Mike mentioned we were very pleased to receive notice from the FDA office of orphan drugs that they had granted the designation to TOCOSOL Paclitaxel at the end of last year for the treatment of non-superficial urothelial cancer. Products designated as orphan drugs are those that are being developed to treat diseases affecting fewer than 200,000 people in the U.S. The Orphan Drug Act provides marketing exclusivity to the first sponsor to obtain approval for an orphan drug, as well as a waiver from the FDA user fee for review of the NDA for the designated orphan indication. The orphan drug designation compliments the fast track designation awarded in 2003. We are pleased that the FDA has recognized the potential of TOCOSOL Paclitaxel to offer meaningful clinical benefit to patients with this unmet need. Our Phase IIb trial in patients with inoperable or metastatic urothelial transitional cell carcinoma continues to expand. In addition to U.S. study sites at major cancer centers in Philadelphia, Baltimore, Cleveland and Seattle, we will soon open new study sites in Spain and England. We believe this expansion in Europe will provide enough patients to be able to report statistically meaningful response rate information by the end of 2005, and we will keep you updated as the study progresses this year.

The Phase IIb breast cancer trial enrolled 47 patients last September and October, all of whom began receiving TOCOSOL Paclitaxel as the initial therapy for their metastatic disease. As of March 4, the investigators are reporting an overall objective response rate in the mid 30 to 40% range, and 35 patients remained on active treatment. However, these results are not yet audited and are subject to change. We anticipate being able to estimate median time to progression by late

summer of this year and follow-up will continue throughout the next two years for the survival end point.

Finally, as Mike mentioned, we were notified last month that the Scientific Program Committee of the American Society of Clinical Oncology accepted the clinical pharmacology study that we conducted in the first half of 2004 for presentation at ASCO 2005 in Orlando in May. In that study the pharamacokinetics and acute safety of Paclitaxel administered as TOCOSOL Paclitaxel and as Taxol were compared in a comprehensive study involving 36 patients with advanced non-hematologic cancers. The study was conducted in Germany, Holland, Belgium, South Africa and the U.S. The largest number of patients was enrolled at the St. Georg Hospital in Hamburg, one of the largest hospitals in Germany. And Professor Axel Hanauske, the head of the cancer center there, will make the presentation at ASCO on Sunday morning, May 15. This was an exceptionally detailed study and the results confirmed that the TOCOSOL formulation is able to deliver substantially more active Paclitaxel into the circulation than can be achieved with Taxol.

Coupled with what we have already seen from previous studies about the ease of use and tolerability of TOCOSOL Paclitaxel given weekly for extended periods, as was done for over a year in some patients in the Phase IIa program, we believe we are assembling a compelling argument to demonstrate that TOCOSOL Paclitaxel will be the Taxane of choice for patients and physicians.

Before I wrap up, let me tell you briefly about Doctor Mary Bolton, who has recently joined us as Vice President for Clinical Research. Mary received her Ph.D. in physiology from the Johns Hopkins University and her M.D. from the Medical College of Pennsylvania. Following a residency in internal medicine, she did post-doctoral research fellowships in pharmacology and toxicology and a clinical fellowship in medical oncology. She is board certified in internal medicine and medical oncology. She was in private practice before joining the faculty of the Lombardi Cancer Center at Georgetown University. She subsequently entered the industry and has led clinical research teams for U.S. Bioscience, Ortho Biotech, Genentech, Cell Therapeutics, and ZymoGenetics. We are delighted that Mary has joined our team and know that she will add substantial value in completing the development and registration of TOCOSOL Paclitaxel and in advancing our pipeline candidates through clinical development. With that, I'll turn the call back to Mike.

Michael A. Martino, President and Chief Executive Officer

Thank you Michael, both for the update and for the significant progress. Securing a partner was a key corporate objective for 2004. We fully expected to achieve this goal and we did not. In retrospect, I can say that uncertainty on the part of prospective partners about our proposed 505b2 regulatory strategy was a major concern for them. We believe this concern can be addressed now that we have received positive guidance from FDA on our pivotal trial program and are moving forward with the special protocol assessment process. Our partnering discussions are continuing in parallel with our discussions with the FDA on the SPA and at this point we believe that finalizing a corporate deal this year is likely to come after the SPA is in place.

Now let's finish up our discussion on 2004 achievements. Our second corporate goal for 2004 was to continue to expand and apply our drug development capabilities to become a more diversified multi-product company. We continue to make good progress on this objective with the development of additional oncology product candidates. Following the presentation of encouraging pre-clinical data on our novel camptothecin derivatives at the American Association for Cancer Research annual meeting in March 2004, we made the decision to move one of those candidates into the later stages of pre-clinical development. Our objective is to move this compound to an IND and then into Phase I studies as expeditiously as possible. Progress, of course, is dependent upon both available financial resources and the emerging pre-clinical data for the compound.

Finally, and perhaps most importantly, throughout 2004 we also strengthened our team with the addition of talented individuals to complement the outstanding team already in place. In January, Lynn Gold joined Sonus as Vice President of Research and Process Development; Sonus veteran Dean Kessler was promoted to Vice President of Preclinical Development; and Neile Grayson was appointed as Vice President of Strategic Planning and Corporate Development. In the middle of the year, Ingrid Rasch joined us as Vice President of Human Resources; and in September, Alan Fuhrman was appointed as Senior Vice President and Chief Financial Officer. Finally, as Michael just mentioned, we were pleased to recently bring Dr. Mary Bolton on board as Vice President of Clinical Research and Development. Again, all in all, 2004 was a year of hard work and steady progress that advanced our goal of creating a company with sustainable value based first and foremost on maximizing our opportunities for TOCOSOL Paclitaxel.

Of course value creation is a process and that process continues in 2005 with objectives that build on our 2004 achievements and take us to the next level as a more capable company and as a more valuable investment. Our objectives are still aimed at developing and realizing the value of TOCOSOL Paclitaxel and expanding and applying our technology to become a more diversified multi-product company. Our specific objectives for 2005 are as follows. First, we are working hard to finalize the TOCOSOL Paclitaxel Phase III special protocol assessment with FDA and we expect to do this within the next three months, of course dependent, as Michael said, on FDA's timeline. Second, our goal is to establish a corporate partnership for TOCOSOL Paclitaxel and we expect to do so this year following agreement of the SPA with FDA. Third, we plan to activate the Phase III trial and we expect to do this in the third quarter, based on availability of necessary financial resources. Fourth, we will continue fast track and orphan drug development of TOCOSOL Paclitaxel in advanced inoperable bladder cancer with the objective of having statistically meaningful data by year-end. Fifth, we will continue our efforts to move internal product candidates to clinical development. We currently expect this next product candidate to be our novel camptothecin compound and our progress with this product will be gated by the ongoing strength of data from preclinical studies and the availability of financial resources.

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

- **QUESTION AND ANSWER SECTION**

Operator: [Operator Instructions] Your first question comes from Matthew Kaplan [Punk, Ziegel & Company].

<Q – Matthew Kaplan>: Hi guys. Thanks for taking my questions.

<A – Michael Martino>: Hi Matt.

<Q – Matthew Kaplan>: Congratulations on the announcement with respect to Synt:em. I think that's terrific news. A couple of questions with respect to getting more of a sense on the SPA status and where that is and you gave us some color in terms of how much longer you think it's going to take but are there any kind of sticking issues

that you need to get past with that?

<A – Michael Martino>: Well, it's difficult to speculate on what FDA may say based on the information we've sent them. At this point, based on our discussions to date, we don't anticipate any "sticky" issues. There is a process to follow and the guidance that we've given is consistent with FDA's guidance on how much that overall process will take. Of course to the extent that we control things, we'd like to move it along faster than that. Michael, would you add anything to that?

<A – Michael Stewart>: No, I agree. I think that we're not going to know much more from them until they get their assessment from their external consultant. The typical SPA process, this division uses a consultant from the ODAC and they do their own internal review themselves, of course, but I don't think we'll be hearing any more details until we get the consultant's opinion.

<Q – Matthew Kaplan>: And I just wanted to make sure I was clear. There is no break up fee or any fee associated with the termination of the Synt:em acquisition?

<A>: That's correct.

<Q – Matthew Kaplan>: Great, and it sounds like you've made terrific progress with respect to the Phase IIb in breast cancer, 47 patients. Could you give us a breakdown in terms of the CRs and the PRs? You mentioned that you had a preliminary unaudited response rate or objective response of mid-30s to mid-40s range. Can you give us a sense in terms of the CR and PR?

<A – Michael Stewart>: Well, I actually don't have the data in front of me so no, I can't tell you what the numbers are. We look at two things. We do a first response assessment after eight weeks of treatment. If there is a response, that individual patient then undergoes the confirmatory assessment four to five weeks later. Everybody then undergoes another assessment at 16 weeks, and so once we actually have all of the best response data, those films are under review by independent radiologists. I think that in the coming weeks, we'll have a much better sense of where they are but actually today, I don't have the breakdown. And this is, as I mentioned, this is the investigator-reported responses that keep coming in every week. So that's why I don't have the numbers right with me.

<Q – Matthew Kaplan>: And could you remind us of the design of this study? Is it weekly dosing?

<A – Michael Stewart>: Yes.

<Q – Matthew Kaplan>: Okay. So it's weekly dosing at what dose?

<A – Michael Stewart>: Starting dose is 120 per square meter every week.

<Q – Matthew Kaplan>: For how many weeks, how long?

<A – Michael Stewart>: Well, they get treated until progressive disease and so that could be easily up to nine months on average, and some women will go longer. Obviously, the last update I had, we had 35 of the 47 still on treatment. Some of those had come off treatment for reasons that were not related to progression; they'd elected not to continue in the study. But in this situation, you would expect that by about nine months, half of the women would have had progressive disease and the others would continue on treatment. So it can go for a while but we hope to have median time to progression by later this summer.

<Q – Matthew Kaplan>: Would this design of this study be – potentially be similar to the confirmatory Phase III that you're talking about with the FDA?

<A – Michael Stewart>: Well, what we're talking about with the FDA, we very clearly – it has been our intention to develop this product for weekly dosing, absolutely.

<Q – Matthew Kaplan>: Thank you. I'll jump back in the queue.

<A – Michael Martino>: Thanks, Matt.

Operator: Your next question comes from Adam Noah [Granite Financial Group].

<Q – Adam Noah>: Thanks for taking my questions.

<A – Michael Martino>: Hi, Adam.

<Q – Adam Noah>: With respect to your partnership with TOCOSOL Paclitaxel, can you be more specific about when you expect it this year, third quarter, fourth quarter?

<A – Michael Martino>: Well, clearly from our perspective if you consider two of Alan's statements, number one that we ended the year with a little over 20 million in cash on the balance sheet, and secondly that over the three years of this pivotal trial – and I want to point out that again the pivotal trial is designed to support a primary objective response endpoint and secondary endpoints related to time to progression and overall duration of survival. And so, particularly the gathering and interpreting and packaging the data on those secondary endpoints could take up to three years. But, as Alan had indicated, we expect the cost of that trial to be in the mid to upper 30 million range. So, we will require additional resources to feel comfortable initiating the trial and making a commitment to patients and investigators. We have been consistent with that – in expression of that philosophy all along. So, we are expecting to be in a position to initiate that trial in Q3, and everything we are doing is aimed towards achievement of that objective.

<Q – Adam Noah>: Do you expect any up front payments? Or do you expect it to be mostly a back-ended deal with taking over the trial costs?

<A – Michael Martino>: Adam, at this point in the negotiations I think everyone is best served if I don't negotiate in public. And I can say that we are – our focus is on securing a partnership with someone who believes as we do, that TOCOSOL Paclitaxel has the potential to be a differentiated Taxane. Someone who agrees with us that that requires a comprehensive and statistically rigorous Phase III program, in addition to an ongoing clinical development program to continue to differentiate the product after that initial approval, and is committed to providing the resources to implement that regulatory and marketing plan. And I would also say that we continue to be willing to – not only willing, but we would prefer to not only stay involved in a meaningful way in the development of the product as well as the commercialization of the product, and we are in discussions around a variety of deal terms and structures to share the opportunities and risk in that type of approach.

<Q – Adam Noah>: I have one more question if I may. You mentioned that you don't want to explain the details of your Phase III trial. I have a question; please explain to me why you think you may need 700 or maybe 800 patients when your competition has been successful with patients in the 400 to 500 range?

<A – Michael Martino>: Well, not all the competition has been successful with patients in the 400 to 500 range.

<Q – Adam Noah>: That's true.

<A – Michael Martino>: I think it depends on – let me give you a businessman's view –

<Q – Adam Noah>: Please.

<A – Michael Martino>: And then I'll turn the clinical science in addition to the business aspects of it over to Michael. You know, certainly when you design a clinical trial, you need to consider the trade-offs. And, you can make bets about your product over-performing the control arm in a primary study. And, if you're lucky and you win that bet, then you get to go on to a secondary endpoint. If you're not lucky and you lose that bet, then you've just wasted the cost involved in studying that number of patients, whatever it is.

The other trade-off that needs to be made of course is that if you have a strategy that is aimed at not just a primary endpoint, but more importantly secondary endpoints that you think are more clinically relevant and meaningful to physicians and patients, then you need to anticipate that along the way there is going to be drop-out of the study and especially in an oncology study. So, even though you may be able to power it up front with a sufficient number of patients to achieve your primary end point, if you don't adequately take into account the drop-out you could effect, you may not end up with enough patients and sufficient power to support your secondary endpoint, which would undermine your long-term strategy.

So, those are the trade-offs that we are considering. Now, I'm sure Michael could number one, express that a lot more eloquently than I just did, but also go into the science of it a little better. Michael?

<A – Michael Stewart>: I don't know that I can say it any better at all. I think that's exactly the point, that when you're starting out a study, you basically have to put in place everything you're going to need by the time that study finishes, and sample sizes that will provide you sufficient power so that you can not only reach conclusions about response rate up front that are truly robust conclusions, but that you can then go on to demonstrate the value, the clinical value, the clinical benefit, that is seen in delaying the progression of disease and extending the duration of people's lives. And if you undersize and under-power, you are never able to demonstrate those benefits. And we believe that this product has the potential to be fully differentiable. It has the potential, eventually, to have the label that shows it's the Taxane of choice. You have to power and size your studies so that you can demonstrate that in the end, when you get there, that you have delayed the time that people have progression of their disease, and you have extended the length of time that they live.

<A – Michael Martino>: You know, I would also daresay, Adam, that we believe, based on our research, that the clinical community would be eager to hear the results of a trial that they view as adequately designed and powered.

<Q – Adam Noah>: Thank you.

<A – Michael Martino>: Thanks for your question. Crystal, any other questions?

Operator: Yes, sir. We also have a follow-up question from Matthew Kaplan.

<Q – Matthew Kaplan>: Hi, guys. Thanks.

<A>: Hi, Matt.

<Q – Matthew Kaplan>: In terms of – a couple of questions. With respect to the bladder cancer indication, could you give us – just lay out a potential timeline for a filing in that indication? Obviously it's a little bit early. We haven't finished the Phase IIb yet. But just give us a sense of that?

<A – Michael Stewart>: I think Matt the thing that's really going to drive that timeline is discussions with the FDA, or with other health ministries, that we can't have until we have those results in hand from the ongoing study. And the reason for that is that normally one would talk about moving to a Phase III comparative study as the pivotal trial. The question in this kind of a disease, where it's really, really hard to study just because there's a paucity of patients, now that means that these are people who really desperately need a better therapeutic choice than the one they've got, but it's not easy to do large studies in this patient population. And so one of the discussions we will want to have with the health authorities is, based on the results of the study that's currently ongoing, what would be the kind of pivotal trial that they would accept? And that could range from what's called pivotal Phase II type sizes up through pivotal Phase III type sizes, and the duration to get to the end of each one of those is rather broad. So I think it's probably easier to talk about the steps that we'll have to go through, rather than to guess when we'll actually be able to make them.

<Q – Matthew Kaplan>: Great. That's fair. Thank you.

<A – Michael Stewart>: Thanks.

<Q – Matthew Kaplan>: And just one other quick follow-up. In terms of – Mike, I think you went through this pretty thoroughly, but when you went through your strategic assessment to make your decision to terminate the Synt:em acquisition, could you give us some more detail with respect to what you saw in TOCOSOL Paclitaxel that helped you make that decision?

<A – Michael Martino>: Well, I don't know whether there's any more detail. Maybe a different way of saying it, that what really converged was a combination of number one, data from our trials, and guidance from our discussions with FDA that put us in a position to define our go-forward plans with a lot more clarity and, we believe, certainty, and at the same time, emerging competitive data which reinforces our belief that we have a very strong competitive product here, and that at this stage in our development as a company, our best interests are served by redoubling our efforts to focus on those opportunities, to maintain the flexibility in terms of allocation of all resources, people and capital being two of the most important ones, on the achievement of that objective. And that's where we are.

<Q – Matthew Kaplan>: Great. Thanks again, and congratulations on your decision.

<A – Michael Martino>: Thank you, Matt.

Operator: Your next question comes from Alan Long [Smith Barney].

<Q – Alan Long>: Hi, everyone. Thanks for taking my questions.

<A – Michael Martino>: Hi, Alan.

<Q – Alan Long>: On the – I might as well follow up on the competitive stuff. Comment – can you provide some color or comment on what the Xyotax data means for Sonus? I'm sure you can go both ways with it, but I'm curious what you have to say about it.

<A – Michael Martino>: Well, you know, I think that a hallmark of our style and our philosophy from the very beginning has been to take the high road and talk about our product and our strategy, and clearly we actively scan the competitive landscape to learn what we can from it. You know, what we have said about TOCOSOL Paclitaxel is – what Michael said is that we believe that we can demonstrate that it's at least a competitive product based on objective response rate and tolerability, but over the long term that we believe we very well may have the potential to prove that it is a more efficacious product. To get there, to implement a strategy that gives us a relatively near-term opportunity to file an NDA under 505b2 on the primary end point objective response, and to continue with that trial, to be in a position to file supplemental claims that are based on statistically rigorous data for the secondary end point, will require 700 evaluable patients, and to achieve 700 evaluable patients, as Michael said, we may well have to enroll up to 800 patients, again, considering the usual drop-out rates from clinical trials. And that's our strategy, and I think if I could add anything it would be that learnings from the competitive landscape have reinforced for us that we have a terrific product, that 505-b2 gives us an accelerated path to a meaningful and competitive approval, and we don't want to try to cut any more corners around that than are absolutely necessary and prudent.

<Q – Alan Long>: Now, hypothetically you're going for a non-inferiority trial, but when you talk about supplemental claims, is one of those hypothetical theoretical claims, could be superiority if the data comes out?

<A – Michael Stewart>: Sure. Sure, I think that's a very important point. You know, one of the – you ask for learnings from others' fortunes and misfortunes, and I think you're exactly on track. One has to look at not only the end points that are postulated for Phase III, but the types of analyses. And you have to make sure that when you are setting up your study, when you're sizing it, when you are reaching agreements with the FDA about what they will use as the basis for approval, you have to pick the right end points, and you have the pick the right types of primary analyses. You have to go for the hardest thing to prove because if that occurs, then all the rest of it will be nested within that. And the FDA is very clear on, you know, they'll give you anything you prove, but you have to prove the first thing first.

<A – Michael Martino>: And as long as you indicate up front that that's what you're going to prove.

<A – Michael Stewart>: Exactly. That's exactly right. The agreement that you reach with the FDA is the end points and the types of analyses and you know, I think that we certainly don't ever see ourselves in the position of having to go back and try to renegotiate post-hope what kind of primary analysis we were going to do.

<A – Michael Martino>: Another way of looking at it Alan, is that, and this is just a general comment based upon the way the statistics work in any trial, if you go for a non-inferiority evaluation of an end-point, no matter what that is, and you can demonstrate that with statistical significance, then you probably have the power also to support a superiority evaluation if the data supports that. However, if you prospectively say you're going to prove superiority, and you don't make it, then you know in our particular case, we think we'd probably be out of luck.

<Q – Alan Long>: Got you. One last question. Assuming Avastin is approved for lung cancer, based on the data released yesterday, how might that affect the SPA and the partnership negotiations?

<A – Michael Stewart>: Yeah, there was an announcement yesterday, and frankly I haven't seen the data to review them, well nobody has, because they haven't been submitted to the FDA yet.

But, I guess I don't understand the issue about how that would affect our SPA, because Avastin is a different product.

<A – Michael Martino>: Yeah, and beyond that Alan, keep in mind that we've said we're going after an indication for which Taxol is approved as a single agent. Our view is that while lung is a significant market opportunity for both Paclitaxel and Docetaxel, the prevailing clinical approach is to use combination therapies. We don't see Avastin changing that. But also, what that says specifically is that lung is probably not our primary target.

<Q – Alan Long>: Yeah, thanks. You know I got the question from my subscribers and I know –

<A – Michael Martino>: Yeah. So, it's a good question. We don't see it implement – we don't see it impacting our near-term strategy.

<Q – Alan Long>: Good deal, thanks.

<A – Michael Martino>: Thanks Alan.

Operator: Your next question comes from the line of Randy Saluck [Meisenbach Capital Management].

<Q – Randy Saluck>: Hey guys.

<A – Michael Martino>: Hi Randy.

<Q – Randy Saluck>: A couple of questions for you. I want to just talk more about – want to hear you talk more about your process for getting a partner, and your timing, because it's certainly been delayed, and you've explained why. Two, how much cash you have on your balance sheet, and I guess that's it. A lot of the questions have been answered.

<A – Michael Martino>: Okay. Well, let's take the data question first, the cash on balance sheet. Alan?

<A – Alan Fuhrman>: Yeah Randy, we had 20.6 million at 12/31/04.

<Q – Randy Saluck>: Okay. So your burn is still within the parameters that you had discussed in the past?

<A – Alan Fuhrman>: Yeah, and – that's right, and we had said earlier in the call that first half of the year we expect a base burn of 1.5 for the first half, and an overall burn for the year of 1.6, but that doesn't include the incremental cost of what our Phase III trials will be, so, I hope that helps.

<Q – Randy Saluck>: So you really need that partner in place by the trials, the commencement of the trials?

<A – Michael Martino>: Well, I think we would need the partner in place, and/or we would need additional financing, and our strategy has clearly been to pursue the partnering discussion.

<Q – Randy Saluck>: Right.

<A – Michael Martino>: Now in terms of the process, again, I don't think it serves anyone to negotiate publicly on this. I would say that we continue in discussions with a handful of potential partners. Some of them have been in discussions with us for a while, and I think are in the process of getting some of their questions answered. For example, the concern I had mentioned in the prepared comments regarding the validity of our regulatory strategy, and I believe we are in the

process of more than addressing that. Some of those potential partners, frankly, are new. Some of them are people who had dropped out earlier in the process, who have come back to discussions. Some of them are truly new. We are continuing with multiple discussions in parallel, and I think your assessment that ideally we would have the partner in place to provide the resources to initiate the Phase III trial in Q3 is a valid assessment.

<A>: Crystal?

Operator: [Operator Instructions]. Your next question comes from David Gruber.

<Q – David Gruber>: Yes, hi Mike.

<A – Michael Martino>: Hi, David.

<Q – David Gruber>: I am just trying to better understand here the price of admission. I mean, you now have with the delay, strategically at least, you now have the PK data, the Phase III – Phase II 3-week data, you have Phase II weekly data, and you have a limited amount of transitional cell data. From the regulatory side, you have the 505-b2 and you are getting an SPA, and then from the competitive side, you know what the story is with APPX and CTIC. So from the negotiating standpoint, would you say the price of admission has gone up significantly over the last 3 to 6 months, and do the potential partners recognize that?

<A – Michael Martino>: Well, again, I don't want to negotiate publicly here. I would back up from the specific question and say that our philosophy all along on this has been that the value of this product would increase over time, with clinical data and with the validation of our regulatory strategy. And so what we have done in the past year is continue to pursue a strategy based on that belief. It has taken no small amount of courage, because there has been enormous pressure on concluding the partnership based on expectations in all fairness that we had originally created. But at the end of the day, our job here, our objective, our fiduciary responsibility is to maximize the value of this asset, and we're pursuing a process with a timeframe that we believe puts us in the best position to do that.

<Q – David Gruber>: Okay. And then from, and again, a very macro question. I know you can't get into the specifics, but are all – the negotiations, is everything more or less on the table, all the way from kind of, licensing deals to co-development to potentially selling the company? I mean, are you looking at all different options here?

<A – Michael Martino>: Well, I would say that everything is on the table. At the same time, I want to add that we are not selling the company. But we are a public company, and we would be – the Board and I would be obligated to consider any responsive offer to acquire the company. But that is not our objective. Our objective is to partner TOCOSOL Paclitaxel through a more conventional partnering vehicle such as a license.

<Q – David Gruber>: Okay. And the timing relating to the SPA, just to add certainty, or is that something that a partner wants, or all of the above?

<A – Michael Martino>: You know, I think it depends upon the individual partner, and what we are balancing, frankly, is whether or not we can get an acceptable deal done with what we have in hand, i.e., minutes of FDA meetings and correspondence. Or, if we believe that there is more upside associated with waiting for that SPA to be finalized. We are prepared to wait for that.

<Q – David Gruber>: Okay. Thank you. That's my questions.

<A – Michael Martino>: Thanks.

Operator: There are no further questions at this time sir.

Michael A. Martino, President and Chief Executive Officer

Okay, Crystal. Thank you. So if there are no further questions, we would like to thank all of you for joining us today. I really believe that our accomplishments and our progress in 2004, as I stated up front, put us in outstanding position to increase our value throughout 2005. As always, we appreciate your support. We look forward to keeping you updated on future developments, and that concludes the call.

Operator: This will conclude today's Sonus Pharmaceuticals conference call. You may now disconnect.