

**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) **July 7, 2005**

SONUS PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or other jurisdiction
of incorporation)

0-26866
(Commission
File Number)

95-4343413
(IRS Employer
Identification No)

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

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

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

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

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

Item 8.01. Other Events.

On July 7, 2005, Sonus Pharmaceuticals, Inc. issued a press release announcing its completion of the Special Protocol Assessment process with the Food & Drug Administration for TOCOSOL Paclitaxel. A copy of the press release making this announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference. The press release shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933.

Item 9.01. Exhibit.

Exhibit 99.1 Press Release, dated July 7, 2005

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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: July 8, 2005

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

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EXHIBIT INDEX

Exhibit No. **Description**



NEWS RELEASE

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

Sonus Pharmaceuticals Completes Special Protocol Assessment (SPA) Process with FDA for TOCOSOL[®] Paclitaxel Phase 3 Clinical Trial in Breast Cancer

BOTHELL, Washington, July 7, 2005—Sonus Pharmaceuticals, Inc. (Nasdaq:SNUS) today announced that the U.S. Food and Drug Administration (FDA) has completed a Special Protocol Assessment (SPA) for the pivotal Phase 3 trial of the Company's lead cancer product candidate, TOCOSOL[®] Paclitaxel. Final written communication from the FDA, dated June 30 and received by the Company on July 5, indicates that the FDA and Sonus have reached agreement on the protocol for the planned Phase 3 study of TOCOSOL Paclitaxel and on the formal written plans for how the study will be conducted. The Phase 3 study will compare TOCOSOL Paclitaxel and Taxol[®] in the treatment of patients with breast cancer.

In the Phase 3 trial, approximately 800 patients will be randomly assigned to treatment with either TOCOSOL Paclitaxel or Taxol, and the effects of each drug on anti-tumor efficacy, tolerability and safety will be assessed. The study progress and interim data evaluations will be overseen by an Independent Data Monitoring Committee comprised of medical oncology and biostatistics experts not associated with the Company.

"This is a significant milestone that represents a tremendous amount of hard work on the part of our entire team at Sonus," said Michael A. Martino, President and CEO of Sonus. "Our corporate development efforts are now focused on securing the necessary financial resources to support the study, and these efforts are ongoing on several fronts. In parallel, we have already begun study start-up activities for the Phase 3 trial."

"Negotiations with investigators and regulatory reviews by health authorities are currently underway in multiple countries where the Phase 3 study will be performed," added Michael B. Stewart, M.D., Senior Vice President and Chief Medical Officer. "We continue to believe that TOCOSOL Paclitaxel may one day offer a new treatment option for cancer patients, and we are very eager to initiate the Phase 3 trial to demonstrate the product's clinical value."

More

The SPA process provides for official FDA evaluation and written guidance on the design, size, and procedures for conducting a pivotal Phase 3 clinical trial and provides the sponsor with written agreement that the design and analysis methods are adequate for a study that is intended to form the basis for a New Drug Application.

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 Phase 3 clinical trials for TOCOSOL Paclitaxel. As discussed in Sonus Pharmaceuticals' filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K filed on March 23, 2005, actual results could differ materially from those projected in the forward-looking statements as a result of the following factors, among others: the company's products will require extensive clinical testing and approval by regulatory authorities; such approvals are lengthy and expensive and may never occur; risks that the company will not be able to initiate Phase 3 clinical trials for TOCOSOL Paclitaxel; risks that clinical studies with TOCOSOL Paclitaxel will not be successful; risks that the FDA may not approve the company's proposed New Drug Application; risks of successful development of additional drug delivery products; and risks that the company may not be successful in obtaining funding from third parties or completing a financing necessary to support the costs and expenses of clinical studies as well as research and development activities. The company undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof.

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