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 21, 2004

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)

TABLE OF CONTENTS

Item 7. Financial Statements and Exhibits.
Item 12. Results of Operations and Financial Condition.
SIGNATURES

EXHIBIT INDEX

EXHIBIT 99.1

Table of Contents

Item 7. Financial Statements and Exhibits.

Exhibit 99.1 Press Release, dated July 21, 2004, issued by Sonus Pharmaceuticals, Inc.

Item 12. Results of Operations and Financial Condition.

On July 21, 2004, Sonus Pharmaceuticals, Inc. issued a press release announcing its financial results for the fiscal quarter ended June 30, 2004. A copy of the press release making this announcement is attached hereto as Exhibit 99.1 and 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.

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 21, 2004 By: /s/ Craig S. E

By: /s/ Craig S. Eudy
Craig S. Eudy
Controller

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release dated July 21, 2004.



NEWS RELEASE

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

SONUS PHARMACEUTICALS REPORTS SECOND QUARTER FINANCIAL RESULTS AND UPDATES CORPORATE PROGRESS

Company finalizing TOCOSOL® Paclitaxel Phase 3 trial plans for FDA's review Phase 2b breast cancer study to be initiated for TOCOSOL Paclitaxel Quarterly call to be held today at 1:30 P.M. PDT/4:30 P.M. EDT

BOTHELL, WA (July 21, 2004) – Sonus Pharmaceuticals, Inc. (Nasdaq:SNUS) today reported financial results for the second quarter and updated its progress on 2004 strategic objectives, including the development of TOCOSOL® Paclitaxel, the Company's lead oncology drug candidate.

"We have now completed patient enrollment in the clinical pharmacology study for TOCOSOL Paclitaxel, an important element of our 505(b)(2) regulatory strategy, which may represent our fastest route to market," said Michael A. Martino, President and CEO of Sonus. "Based on early evaluation of the data, we believe that TOCOSOL Paclitaxel is delivering at least as much active drug as Taxol®, the approved comparative drug, and that these results will support our strategy of seeking approval for TOCOSOL Paclitaxel through a 505(b)(2) New Drug Application. We are completing our analyses of the clinical pharmacology data and finalizing the details of our proposal for Phase 3 clinical testing of TOCOSOL Paclitaxel, with the goal of submitting these plans to the FDA before the end of summer."

Additionally, the Company reported that it is initiating a Phase 2b study of TOCOSOL Paclitaxel in patients with metastatic breast cancer to generate data in one of the primary cancers treated with paclitaxel-based therapies. This Phase 2b trial will use weekly dosing of TOCOSOL Paclitaxel at 120 mg/m² with the purpose of evaluating the effect of increased dose density in breast cancer patients.

During the second quarter, Sonus presented results of three Phase 2a clinical trials of TOCOSOL Paclitaxel in non-small cell lung, bladder and ovarian cancers at the annual meeting in June of the American Society of Clinical Oncology (ASCO). These studies showed that in addition to potentially improving anti-tumor efficacy, treatment with TOCOSOL Paclitaxel may not be limited by severe side effects associated with current paclitaxel-based products. TOCOSOL Paclitaxel appears to be well tolerated, and most patients received their intended weekly therapy

More...

without interruption, including some patients who have been treated with TOCOSOL Paclitaxel for over 52 weeks. As reported prior to ASCO, the Phase 2a data showed promising objective response rates, including complete and partial responses, in treatment of patients whose primary chemotherapy had failed. New data presented at ASCO showed encouraging trends for time-to-disease progression and one-year survival.

Sonus also reported that based on encouraging anti-tumor data in animal models, which were presented at the American Association for Cancer Research Annual Meeting in March, it has made the decision to advance a new camptothecin derivative through final preclinical studies with the goal of initiating clinical testing in 2005. By formulating a camptothecin derivative with the Company's TOCOSOL technology, Sonus may be able to produce a drug that has increased anti-tumor activity with a safety profile that is equal to, if not better than, marketed products. There are two camptothecin analogs on the market today that are approved for the treatment of colorectal, ovarian and lung cancers and account for nearly \$800 million in annual worldwide sales.

Second Quarter Financial Results

For the second quarter of 2004, Sonus reported a net loss of \$3.8 million, or \$0.19 per share, compared with a net loss of \$3.1 million, or \$0.22 per share, for the second quarter of 2003. For the first six months of 2004, the Company reported a net loss of \$7.3 million, or \$0.39 per share, compared with a net loss of \$5.4 million, or \$0.39 per share, for the same period of 2003. The higher net loss for the 2004 second quarter and year-to-date financial results reflected planned increases in R&D spending to support additional clinical studies for TOCOSOL Paclitaxel as well as other product and corporate development activities.

Cash and marketable securities totaled \$28.7 million at June 30, 2004 compared with \$19.7 million at December 31, 2003. The increase from year-end was due primarily to the \$14.4 million of net proceeds from the Company's private placement in May 2004. Sonus expects that its net cash burn rate will average approximately \$1.5 million per month for 2004 as the Company continues to execute the clinical and regulatory plans for TOCOSOL Paclitaxel and invest in corporate development initiatives to bring additional product candidates forward.

Quarterly Conference Call

Sonus will host its quarterly conference call today, Wednesday, July 21, at 1:30 P.M. Pacific Time/4:30 P.M. Eastern Time. The call will be web cast live and archived on the Company's web site at www.sonuspharma.com/events.html. A telephone replay of the conference call will also be available for one week at (800) 642-1687 or (706) 645-9291 for international calls; Pass code: 8619387.

About Sonus Pharmaceuticals

Headquartered near Seattle, Sonus Pharmaceuticals, Inc. is focused on the development of novel drugs for the oncology market that may offer improved administration, tolerability, safety and effectiveness. The Company's lead product is TOCOSOL® Paclitaxel, an injectable, ready-to-use formulation of the leading anti-cancer drug paclitaxel. TOCOSOL Paclitaxel has been designed to overcome the limitations associated with current paclitaxel-based chemotherapies, including time consuming and expensive preparation of the products prior to administration, long infusion times and undesirable or treatment-limiting side effects. Sonus completed patient

More....

enrollment in Phase 2a studies of TOCOSOL Paclitaxel in 2003 and has initiated additional clinical studies to provide data that will be the basis for new drug applications submitted to the U.S. Food and Drug Administration (FDA) and other regulatory authorities around the world. 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 April 21, 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; such approvals are lengthy and expensive and may never occur; risks that clinical studies with TOCOSOL Paclitaxel will not be successful; and risks of successful development of additional drug delivery products.

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

###

More...

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

| | | Three Months Ended June 30, | | Six Months Ended June 30, | |
|-----------------------------|--------------------|--------------------------------|------------|------------------------------|--|
| | 2004 | 2003 | 2004 | 2003 | |
| Revenue | \$ — | \$ — | \$ — | \$ 25 | |
| Operating expenses: | | | | | |
| Research and development | 2,660 | 2,314 | 5,228 | 3,946 | |
| General and administrative | 1,157 | 802 | 2,203 | 1,529 | |
| Total operating expenses | 3,817 | 3,116 | 7,431 | 5,475 | |
| Operating loss | (3,817) | (3,116) | (7,431) | (5,450) | |
| Interest income, net | 56 | 30 | 91 | 90 | |
| Loss before taxes | (3,761) | (3,086) | (7,340) | (5,360) | |
| Taxes | <u> </u> | | | <u> </u> | |
| Net loss | \$ <u>(3,761</u>) | \$ (3,086) | \$ (7,340) | \$ (5,360) | |
| Net loss per share: | | | | | |
| Basic | \$ (0.19) | \$ (0.22) | \$ (0.39) | \$ (0.39) | |
| Diluted | \$ (0.19) | \$ (0.22) | \$ (0.39) | \$ (0.39) | |
| Shares used in calculation: | | | | | |
| Basic | 19,970 | 13,741 | 19,008 | 13,719 | |
| Diluted | 19,970 | 13,741 | 19,008 | 13,719 | |

Condensed Balance Sheets (in thousands)

| | June 30, 2004 | December 31, 2003 |
|--|------------------|----------------------|
| | (unaudited) | |
| Assets: | | |
| Cash and marketable securities | \$ 28,728 | \$ 19,664 |
| Other current assets | 250 | 198 |
| Property and equipment, net | 1,527 | 1,606 |
| Total assets | \$ 30,505 | \$ 21,468 |
| Liabilities and stockholders' equity: | | |
| Accounts payable and accrued expenses | \$ 2,371 | \$ 1,886 |
| Lease obligations | 198 | 272 |
| Stockholders' equity | 27,936 | 19,310 |
| Total liabilities and stockholders' equity | \$ 30,505 | \$ 21,468 |