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**U.S. SECURITIES AND EXCHANGE COMMISSION**  
Washington D.C. 20549

**FORM 10-Q**

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2002

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES  
EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_ TO \_\_\_\_\_

Commission file number 0-26866

**Sonus Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**95-4343413**  
(I.R.S. Employer Identification Number)

**22026 20th Ave. SE, Bothell, Washington 98021**  
(Address of Principal Executive Offices)

**(425) 487-9500**  
(Registrant's Telephone Number, Including Area Code)

Indicate by check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

State the number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date.

Class	Outstanding at May 1, 2002
Common Stock, \$.001 par value	13,650,998

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**Part I. Financial Information****Item 1. Financial Statements****Sonus Pharmaceuticals, Inc.  
Balance Sheets**

	March 31, 2002	December 31, 2001
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,928,484	\$ 455,073
Marketable securities	22,177,207	14,668,841
Other current assets	345,678	343,057
Total current assets	25,451,369	15,466,971
Equipment, furniture and leasehold improvements, net of accumulated depreciation of \$3,766,967 and \$3,698,552	831,940	396,711
Total assets	\$ 26,283,309	\$ 15,863,682
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,326,861	\$ 1,198,552
Current portion of lease obligations	18,712	—
Total current liabilities	1,345,573	1,198,552
Lease obligations, less current portion	106,525	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 authorized; no shares issued or outstanding	—	—
Common stock; \$.001 par value; 30,000,000 shares authorized; 13,638,169 and 11,650,797 shares issued and outstanding at March 31, 2002 and December 31, 2001, respectively	55,953,453	43,302,286
Accumulated deficit	(31,090,548)	(28,676,864)
Accumulated other comprehensive income (loss)	(31,694)	39,708
Total stockholders' equity	24,831,211	14,665,130
Total liabilities and stockholders' equity	\$ 26,283,309	\$ 15,863,682

See accompanying notes.

**Sonus Pharmaceuticals, Inc.**  
**Statements of Operations**  
**(Unaudited)**

	Three Months Ended March 31,	
	2002	2001
Revenues:		
Contract and licensing revenue	\$ 25,000	\$ 1,095,528
Operating expenses:		
Research and development	1,681,343	1,168,062
General and administrative	865,139	696,715
Total operating expenses	<u>2,546,482</u>	<u>1,864,777</u>
Operating loss	(2,521,482)	(769,249)
Interest income (expense):		
Interest income	108,842	141,884
Interest expense	(1,044)	(10,208)
Total interest income, net	<u>107,798</u>	<u>131,676</u>
Loss before taxes	(2,413,684)	(637,573)
Taxes	—	100,000
Net loss	<u>\$ (2,413,684)</u>	<u>\$ (737,573)</u>
Basic and diluted net loss per share	\$ (0.18)	\$ (0.08)
Shares used in computation of basic and diluted net loss per share	13,264,017	9,202,917

See accompanying notes.

**Sonus Pharmaceuticals, Inc.**  
**Statements of Cash Flows**  
**(Unaudited)**

	Three Months Ended March 31,	
	2002	2001
<b>Operating activities:</b>		
Net loss	\$ (2,413,684)	\$ (737,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	68,415	80,767
Amortization of net premium (discount) on marketable securities	90,508	(8,550)
Realized losses on marketable securities	6,869	—
Changes in operating assets and liabilities:		
Other current assets	(2,621)	(28,153)
Accounts payable and accrued expenses	128,309	124,933
Net cash used in operating activities	(2,122,204)	(568,576)
<b>Investing activities:</b>		
Purchases of capital equipment and leasehold improvements	(503,644)	(18,906)
Purchases of marketable securities	(14,024,840)	(2,698,258)
Proceeds from sales of marketable securities	1,847,695	242,095
Proceeds from maturities of marketable securities	4,500,000	3,470,303
Net cash (used in) provided by investing activities	(8,180,789)	995,234
<b>Financing activities:</b>		
Proceeds from lease obligations	125,237	—
Proceeds from bank line of credit	—	5,000,000
Repayment of bank line of credit	—	(5,000,000)
Proceeds from issuance of common stock	12,651,167	19,040
Net cash provided by financing activities	12,776,404	19,040
Increase in cash and cash equivalents for the period	2,473,411	445,698
Cash and cash equivalents at beginning of period	455,073	1,696,609
Cash and cash equivalents at end of period	2,928,484	2,142,307
Marketable securities at end of period	22,177,207	5,772,060
Total cash, cash equivalents and marketable securities	\$ 25,105,691	\$ 7,914,367
<b>Supplemental cash flow information:</b>		
Interest paid	\$ 1,044	\$ 10,208
Income taxes paid	\$ —	\$ 100,000

See accompanying notes.

**Sonus Pharmaceuticals, Inc.**  
**Notes to Financial Statements**  
**(Unaudited)**

**1. Basis of Presentation**

The unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented.

The financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Form 10-K for the year ended December 31, 2001 and filed with the Securities and Exchange Commission on March 5, 2002.

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), which requires a change in accounting for goodwill and certain other intangible assets. SFAS 142 is effective for fiscal years beginning after December 15, 2001. SFAS 142 is not applicable to the Company, as it has no goodwill or other intangible assets.

In August 2001, the FASB issued Statement of Financial Accounting Standard No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS 144), which addresses financial accounting and reporting for impairment or disposal of long-lived assets and supersedes SFAS 121. SFAS 144 is effective for fiscal years beginning after December 15, 2001. The Company adopted SFAS 144 as of January 1, 2002. The adoption of SFAS 144 had no impact on the Company's results of operations or financial position.

**2. Comprehensive Income (Loss)**

	Three months ended March 31,	
	2002	2001
Net income (loss)	\$(2,413,684)	\$(737,573)
Unrealized gains (losses) on marketable securities	(71,402)	7,984
Comprehensive income (loss)	\$(2,485,086)	\$(729,589)

**3. Common Stock**

In January 2002, the Company sold 1.9 million shares of common stock in a private placement transaction for gross proceeds of \$13.6 million (\$12.5 million net of transaction costs). In connection with the placement, the Company issued warrants to purchase up to 385,800 shares of common stock. The warrants are exercisable at \$9.40 per share and expire in January 2007.

## Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Forward-Looking Statements

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

- Progress and results of clinical trials;
- Anticipated Investigational New Drug filings and future clinical trials;
- Market acceptance of our products and the potential size of these markets;
- Our anticipated future capital requirements and the terms of any capital financing;
- Timing and amount of future contractual payments, product revenues and operating expenses; and
- Anticipated outcome or financial impact of potential legal matters.

While these forward-looking statements made by us are based on our current beliefs and judgement, they are subject to risks and uncertainties that could cause actual results to vary from the projections in the forward-looking statements. You should consider the risks below carefully in addition to other information contained in this report before purchasing shares of our common stock. If any of the risks listed below occur, they could seriously harm our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

The discussion and analysis set forth in this document contains trend analysis, discussions of regulatory status and other forward-looking statements. Actual results could differ materially from those projected in the forward-looking statement as a result of the following factors, among others:

- Dependence on the development and commercialization of products;
- History of operating losses and uncertainty of future financial results;
- Uncertainty of governmental regulatory requirements and lengthy approval process;
- Dependence on third parties for funding, clinical development, manufacturing and distribution;
- Uncertainty of U.S. or international legislative or administrative actions;
- Future capital requirements and uncertainty of additional funding;
- Competition and risk of technological obsolescence;
- Limited manufacturing experience and dependence on a limited number of contract manufacturers and suppliers;
- Ability to obtain and defend patents and protect trade secrets;
- Limitations on third-party reimbursement for medical and pharmaceutical products;
- Dependence on key employees;
- Continued listing on the Nasdaq National Market; and
- Volatility in the value of our common stock.

Certain of these risk factors are discussed in more detail in our Annual Report on Form 10-K for the year ended December 31, 2001.

### MD&A Overview

In Management's Discussion and Analysis of Financial Condition and Results of Operations we explain the general financial condition and the results of operations for our Company, including:

- An overview of our business;
- Results of operations and why those results are different from the prior year; and
- The capital resources our Company currently has and possible sources of additional funding for future capital requirements.

## Business Overview

The Company is applying its expertise in drug delivery to make therapeutic drugs safer, easier to administer and more effective. The Company's TOCOSOL™ drug delivery technology, a vitamin E-based oil-in-water emulsion, is broadly applicable to multiple drugs, diseases and dosage forms. We currently have a cancer therapy product, TOCOSOL Paclitaxel (formerly known as S-8184), in Phase 2 clinical trials, and we also have several active compounds under investigation in therapeutic areas that target cancer, cardiovascular disease, diabetes, and infection.

The Company's first application of its TOCOSOL drug delivery technology is an injectable paclitaxel emulsion formulation, TOCOSOL Paclitaxel. Paclitaxel is the active ingredient in the world's leading cancer drug, Taxol®, which is approved in the U.S. for the treatment of breast, ovarian and non-small cell lung tumors. We filed an Investigational New Drug Application, or IND, for TOCOSOL Paclitaxel with the U.S. Food and Drug Administration (FDA) in September 2000 and initiated a Phase 1 human clinical study in December 2000. We expect to complete the Phase 1 study for TOCOSOL Paclitaxel by mid-2002. In March 2002, we initiated four Phase 2 studies for TOCOSOL Paclitaxel, to evaluate efficacy in non-small cell lung, ovarian, bladder and colorectal cancers in patients that have not previously had taxane chemotherapy treatments. We expect patient enrollment in these Phase 2 studies to continue through mid-2003.

The objectives of the Phase 1 study for TOCOSOL Paclitaxel are to determine the side effect/toxicity profile, maximum tolerated dose, and pharmacokinetic profile and to evaluate for preliminary evidence of anti-tumor activity. To date, we have enrolled patients with a wide variety of cancers. Preliminary Phase 1 results suggest that TOCOSOL Paclitaxel may provide safety and convenience advantages for both patients and physicians including a reduction in side effects, a reduction or elimination of steroid premedications and a reduction in the administration time using a ready-to-use formulation in a single, quick injection administered in less than 15 minutes compared to the three-hour infusion of existing formulations of paclitaxel. Based on preclinical and clinical studies, we also believe there may be potential efficacy benefits of TOCOSOL Paclitaxel that may result from higher concentrations of the drug delivered to the tumor and higher sustained dose density within the tumor. In Phase 1 tests measuring levels of paclitaxel in blood, a bolus injection of TOCOSOL Paclitaxel resulted in higher peak drug concentrations, higher total drug exposure and slower clearance times compared with published literature for a three-hour infusion of Taxol. However, the Phase 1 study is primarily designed to evaluate safety and clinical pharmacology, not efficacy, and there can be no assurance that Phase 2 studies will demonstrate higher efficacy than currently marketed products.

On April 8, 2002, the Company presented data from the Phase 1 study on TOCOSOL Paclitaxel at the American Association for Cancer Research Annual Meeting. As of that date, 36 patients were enrolled, 33 of which were evaluable, meaning that they were on study for at least six weeks and had at least two CT imaging scans to check the progress of their cancer. Of the 33 evaluable patients as of April 8, 2002, 12 patients had a tumor response to TOCOSOL Paclitaxel. Of these 12 patients, three had partial responses (tumor area reduction of more than 50%), two patients had minor responses (tumor area reduction of less than 50%) and seven patients had stable disease, meaning that their cancer progression has been halted. Of potential significance is that two of the three partial responses were further defined as durable partial responses, which is a reduction of 50% or more in tumor area for more than six months. These two patients both failed multiple other prior chemotherapy treatments, and one of the patients with non-small cell lung cancer had previously received both Taxol and Taxotere®, another taxane product. The other patient with a durable partial response has colorectal cancer, which is an indication where Taxol has not been historically effective. All of the patients in the Phase 1 study have advanced cancers and no other therapeutic options.

Based on results to date, the maximum tolerated dose (MTD) has been determined to be at least as high as Taxol, which is dosed at 175 mg/m<sup>2</sup> once every three weeks. Patient enrollment continues in the Phase 1 study to evaluate if a higher MTD can be reached. Dose limiting toxicities seen to date include myalgia (muscle aches), fatigue, and neutropenia (low white cell count). No Grade 3 or 4 neuropathy has been seen at doses up to 200 mg/m<sup>2</sup>. The Company will present additional data on the Phase 1 study for TOCOSOL Paclitaxel at the American Society of Clinical Oncology Annual Meeting to be held May 18-21, 2002.

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Phase 2 studies for TOCOSOL Paclitaxel were initiated in the late March of 2002. The Phase 2 program is designed to evaluate the efficacy of TOCOSOL Paclitaxel in specific tumor types. Our goal is to obtain a clear measure of efficacy with TOCOSOL Paclitaxel and to quickly determine the indications where the product shows the greatest efficacy. The first four Phase 2 studies will evaluate TOCOSOL Paclitaxel in non-small cell lung, ovarian, bladder and colorectal cancers using weekly dosing. These will be single agent, second line studies enrolling patients that have not previously had taxane chemotherapy treatments. Initial efficacy data is expected in the second half of 2002 and patient enrollment is expected to continue through mid-2003.

In addition to TOCOSOL Paclitaxel, we are evaluating other products and additional therapeutic drug formulations to expand our TOCOSOL drug delivery technology. We currently have several active compounds under investigation in therapeutic areas that target cancer, cardiovascular disease, diabetes, and infection. In addition to injectable dosage forms, we are also seeing preliminary evidence supporting oral administration using the TOCOSOL technology platform in certain of these compounds. Our objective is to file two Investigational New Drug (IND) applications with the FDA by the end of 2002. Our investigation and research and development efforts on these are preliminary and we cannot give any assurance that any of these compounds will be successful or that INDs will be filed.

### **Results of Operations**

Our results of operations have varied and will continue to vary significantly and depend on, among other factors:

- Timing of payments under contractual and license agreements;
- Entering into additional contractual agreements;
- Timing and costs of clinical trials, legal matters and expenses related to product development; and
- Timing of regulatory approvals.

To date, our reported revenues have been derived from payments received under contractual and license agreements with third parties. Revenues were \$25,000 for the first quarter of 2002 versus \$1.1 million for the first quarter of 2001. The first quarter of the prior year included a \$1.0 million non-refundable license fee payment received under our ultrasound contrast patent license agreement with Chugai Pharmaceutical Co. Ltd. (Chugai).

Total operating expenses were \$2.5 million for the first quarter of 2002 compared with \$1.9 million for the first quarter of 2001. The increase in operating expenses from the prior year was primarily due to higher research and development expenses (\$1.7 million in the first quarter of 2002 compared to \$1.2 million in the first quarter of 2001). This increase was largely due to increased activity related to the manufacture and development of our lead cancer therapy product, TOCOSOL Paclitaxel, as the drug advances through clinical trials as well as increased personnel costs necessary to support new product development. General and administrative expenses were also higher (\$865,000 in the first quarter of 2002 compared to \$697,000 in the first quarter of 2001) primarily due to higher personnel costs.

We anticipate total operating expenses for the next several quarters will increase over the first quarter of 2002 levels due to the recent initiation of the Phase 2 studies with TOCOSOL Paclitaxel as well as expanded new product development activities. Operating expenses for the full year 2002 are expected to be approximately \$13.0 to \$14.0 million.

Interest income, net of interest expense of \$1,000, was \$108,000 for the first quarter of 2002 compared with \$132,000, net of interest expense of \$10,000, for the same period of the prior year. The decrease in net interest income was primarily due to significantly lower interest rates during the first quarter of 2002 offset partially by higher levels of invested cash in the current year.

In the first quarter of 2001, we incurred Japanese withholding taxes of \$100,000, representing 10% of the \$1.0 million license fee paid by Chugai in January 2001.

## Liquidity and Capital Resources

We have historically financed operations with payments under contractual agreements with third parties and proceeds from equity financings. At March 31, 2002, we had cash, cash equivalents and marketable securities of \$25.1 million compared to \$15.1 million at December 31, 2001. The increase was primarily due to \$12.5 million of net proceeds from a private placement of common stock in January 2002, offset in part by the net loss for the quarter of \$2.4 million.

We expect that our cash needs will increase in future periods due to development costs associated with our TOCOSOL drug delivery products. Based on our current operating plan, including planned clinical trials and other product development costs, we estimate that existing cash and marketable securities will be sufficient to meet our cash requirements through 2003. However, we will need additional funding to complete additional clinical trials and regulatory approval of TOCOSOL Paclitaxel and to fund other product development activities beyond this timeframe. Accordingly, we intend to seek additional funding through available means, which may include debt and/or equity financing or funding under additional third party collaborative agreements. Our future capital requirements depend on many factors including:

- The progress of our research and development programs and clinical trials;
- The time and costs required to complete clinical trials and obtain regulatory approvals;
- The ability to raise additional funds through private placement equity financing;
- The ability to attract and retain new collaborative agreement partners;
- The ability to obtain funding under contractual and licensing agreements; and
- The costs of filing, prosecuting, enforcing and defending patents, patent applications, patent claims and trademarks.

We cannot give assurance that additional financing will be available on acceptable terms, if at all. Any equity financing would likely result in dilution to our existing stockholders and debt financing, if available, may include restrictive covenants. If we are unable to raise additional financing, we may be required to curtail or delay the development of our products and new product research and development, which could seriously harm our business.

## Critical Accounting Policies and Estimates

The preparation of the financial statements requires management to make estimates and assumptions. On an on-going basis, management evaluates its estimates and judgements including those related to revenue recognition and research and development costs. Management bases its estimates and judgements on historical experience and on various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among others, affect its more significant judgements and estimates used in the preparation of its financial statements.

- *Revenue Recognition.* Since inception, the Company has generated revenues from collaborative agreements, licensing fees and from the assignment of developed and patented technology. Revenue is recorded as earned based on the performance requirements of the contract, generally as the services are performed. The Company recognizes revenue from non-refundable, up front license fees and proceeds from the assignment of technology when delivery has occurred and no future obligations exist. Royalties from licensees are based on third-party sales and recorded as earned in accordance with contract terms, when third-party results are reliably measured and collection is reasonably assured. Payments received for which the earnings process is not complete are classified as deferred revenue.
- *Research and Development Costs.* These items including personnel costs, supplies, depreciation and other indirect research and development costs are expensed as incurred. In instances where the Company enters

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into collaborative agreements with third parties, costs are expensed the earlier of when amounts are due or when services are performed.

### Item 3. Market Risk

The market risk inherent in our marketable security portfolio represents the potential loss that could arise from adverse changes in interest rates. If market rates hypothetically increase immediately and uniformly by 100 basis points from levels at March 31, 2002, the decline in the fair value of the investment portfolio would not be material. Because we have the ability to hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates.

## Part II. Other Information

### Item 2. Changes in Securities and Use of Proceeds

(c) The following is a summary of transactions by the Company during the fiscal quarter ended March 31, 2002, involving sales of the Company's securities that were not registered under the Securities Act of 1993 (the "Securities Act"):

On January 18, 2002, the Company sold 1,929,000 shares of its common stock and warrants to purchase up to 385,800 shares of its common stock at an exercise price of \$9.40 per share under the terms of a Securities Purchase Agreement to accredited investors in conformity with rule 506 under Regulation D and under Section 4 (2) of the Securities Act for an aggregate purchase price of approximately \$13.6 million, resulting in net proceeds to the Company of approximately \$12.5 million. The Company and the investors concurrently entered into a Registration Rights Agreement under which the Company has registered such 2,314,800 shares for resale under the Securities Act.

### Item 4. Submission of Matters to a Vote of Security Holders

Our Annual Meeting of Stockholders was held on April 23, 2002. At the Annual Meeting there were two matters submitted to a vote of security holders. Proxies were solicited pursuant to Regulation 14A of the Securities Exchange Act of 1934. There was no solicitation in opposition to management's nominees as listed in the proxy statement. Each director nominated and all other proposals submitted to a vote passed and the voting outcome of each proposal is as follows:

1. Election of the following five (5) directors to serve until the next annual meeting of stockholders or until their successors are elected and have qualified to serve as directors:

Nominee	For	Abstain
Michael A. Martino	9,736,157	37,903
George W. Dunbar, Jr.	9,736,127	37,933
Christopher S. Henney, Ph.D., D.Sc	9,206,127	567,933
Robert E. Ivy	9,737,027	37,033
Dwight Winstead	9,737,127	36,933

2. Ratification of Ernst & Young LLP as independent auditors of the Company for the fiscal year ending December 31, 2002:

For: 9,754,682

Against: 5,993

Abstain: 13,385

**Items 1, 3, 5 and 6 are not applicable and have been omitted.**

**SIGNATURES**

In accordance with the requirements of the Securities Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**SONUS PHARMACEUTICALS, INC**

Date: May 14, 2002

By: /s/ Richard J. Klein

Richard J. Klein  
Vice President, Finance and  
Chief Financial Officer  
(Principal Financial and Accounting Officer)