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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 June 30, 2003

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 registrant (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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at August 4, 2003
Common Stock, \$.001 par value	17,679,308

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

### SIGNATURES

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

	June 30, 2003	December 31, 2002
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 11,270,716	\$ 16,334,004
Other current assets	222,123	289,909
Total current assets	11,492,839	16,623,913
Property and equipment, net	1,487,023	1,310,390
Total assets	\$ 12,979,862	\$ 17,934,303
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,230,969	\$ 1,800,786
Current portion of lease obligations	144,321	137,602
Total current liabilities	2,375,290	1,938,388
Lease obligations, less current portion	198,106	271,987
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; 13,749,237 and 13,691,547 shares issued and outstanding at June 30, 2003 and December 31, 2002, respectively	56,072,891	56,010,950
Accumulated deficit	(45,673,156)	(40,312,665)
Accumulated other comprehensive income	6,731	25,643
Total stockholders' equity	10,406,466	15,723,928
Total liabilities and stockholders' equity	\$ 12,979,862	\$ 17,934,303

See accompanying notes.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2003	2002	2003	2002
Revenues	\$ —	\$ —	\$ 25,000	\$ 25,000
Operating expenses:				
Research and development	2,314,195	2,832,678	3,945,828	4,514,021
General and administrative	802,232	861,149	1,529,683	1,726,288
Total operating expenses	3,116,427	3,693,827	5,475,511	6,240,309
Operating loss	(3,116,427)	(3,693,827)	(5,450,511)	(6,215,309)
Interest income (expense):				
Interest income	42,337	157,072	115,072	265,914
Interest expense	(12,055)	(6,836)	(25,052)	(7,880)
Total interest income, net	30,282	150,236	90,020	258,034
Loss before taxes	(3,086,145)	(3,543,591)	(5,360,491)	(5,957,275)
Taxes	—	—	—	—
Net loss	\$ (3,086,145)	\$ (3,543,591)	\$ (5,360,491)	\$ (5,957,275)
Basic and diluted net loss per share	\$ (0.22)	\$ (0.26)	\$ (0.39)	\$ (0.44)
Shares used in computation of basic and diluted net loss per share	13,740,747	13,649,379	13,718,870	13,456,693

See accompanying notes.

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

	Six Months Ended June 30,	
	2003	2002
<b>Operating activities:</b>		
Net loss	\$ (5,360,491)	\$ (5,957,275)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	181,697	163,716
Amortization of net premium on marketable securities	14,756	143,430
Changes in operating assets and liabilities:		
Other current assets	67,786	(54,313)
Accounts payable and accrued expenses	430,183	885,204
Net cash used in operating activities	(4,666,069)	(4,819,238)
<b>Investing activities:</b>		
Purchases of capital equipment and leasehold improvements	(358,330)	(1,062,516)
Purchases of marketable securities	(4,910,711)	(18,491,874)
Proceeds from sales of marketable securities	1,386,531	3,831,968
Proceeds from maturities of marketable securities	13,550,000	7,372,000
Net cash provided by (used in) investing activities	9,667,490	(8,350,422)
<b>Financing activities:</b>		
Proceeds from lease obligations	—	366,885
Payments on lease obligations	(67,162)	(17,733)
Proceeds from issuance of common stock	61,941	12,683,219
Net cash provided by (used in) investing activities	(5,221)	13,032,371
Change in cash and cash equivalents for the period	4,996,200	(137,289)
Cash and cash equivalents at beginning of period	378,007	455,073
Cash and cash equivalents at end of period	5,374,207	317,784
Marketable securities at end of period	5,896,509	21,789,809
Total cash, cash equivalents and marketable securities	\$11,270,716	\$ 22,107,593
<b>Supplemental cash flow information:</b>		
Interest paid	\$ 25,052	\$ 7,880
Income taxes paid	\$ —	\$ —

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, 2002 and filed with the Securities and Exchange Commission on March 10, 2003.

**2. Comprehensive Income (Loss)**

	Three months ended June 30,		Six months ended June 30,	
	2003	2002	2003	2002
Net income (loss)	\$(3,086,145)	\$(3,543,591)	\$(5,360,491)	\$(5,957,275)
Unrealized gain (loss) on marketable securities	(8,099)	47,894	(18,912)	(23,508)
Comprehensive income (loss)	<u>\$(3,094,244)</u>	<u>\$(3,495,697)</u>	<u>\$(5,379,403)</u>	<u>\$(5,980,783)</u>

**3. Cash, Cash Equivalents and Marketable Securities**

Cash, cash equivalents and marketable securities consist of the following:

	June 30, 2003	December 31, 2002
Cash and cash equivalents	\$ 5,374,207	\$ 378,007
Marketable securities	5,896,509	15,955,997
	<u>\$11,270,716</u>	<u>\$16,334,004</u>

**4. Accounting for Stock Options**

Under the provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," companies may continue to follow Accounting Principles Board Opinion No. 25 (APB 25) in accounting for stock-based compensation and provide footnote disclosure of the proforma impact of expensing stock options. We have elected to follow the disclosure-only provisions of SFAS

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No. 123 and continue to apply APB 25 and related interpretations in accounting for our stock option plans. Under the provisions of APB 25 and related interpretations, employee stock-based compensation expense is recognized based on the intrinsic value of the option on the date of grant (the difference between the market value of the underlying common stock on the date of grant and the option exercise price, if any). At June 30, 2003 we had several stock-based employee compensation plans. All options granted under these plans had exercise prices equal to the market value of the underlying common stock on the date of grant and therefore, in accordance with APB 25, no stock-based employee compensation cost has been recorded.

As required under SFAS 123, the following table illustrates the effect on net loss and net loss per share if we had applied the fair value expense recognition provision of SFAS 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	Three months ended June 30,		Six months ended June 30,	
	2003	2002	2003	2002
Net loss, as reported	\$ (3,086,145)	\$ (3,543,591)	\$ (5,360,491)	\$ (5,957,275)
Add: Stock-based employee compensation expense included in reported net loss	—	—	—	—
Deduct: Stock-based employee compensation expense determined under the fair value based method	(139,732)	(654,855)	(346,526)	(802,436)
Pro forma net loss	\$ (3,225,877)	\$ (4,198,446)	\$ (5,707,017)	\$ (6,759,711)
Earnings per share:				
Basic and diluted-as reported	\$ (0.22)	\$ (0.26)	\$ (0.39)	\$ (0.44)
Basic and diluted-pro forma	\$ (0.23)	\$ (0.31)	\$ (0.42)	\$ (0.50)

The fair value of each option used in the calculations under SFAS 123 is estimated using the Black-Scholes option pricing model. The assumptions used in this model include (1) the stock price at grant date, (2) the exercise price, (3) an estimated option life of four years, (4) no expected dividends for each period presented, (5) stock price volatility factor of 1.135 and 1.154 as of June 30, 2003 and 2002, respectively, and (6) a risk-free interest rate of 2.36% and 3.82% as of June 30, 2003 and 2002, respectively.

## 5. Subsequent Event

In July 2003, the Company sold 3.9 million shares of common stock in a private placement transaction for gross proceeds of \$14.2 million (approximately \$13.1 million net of transaction costs). As part of the private placement, the Company issued warrants to purchase up to 1.95 million shares of common stock. The common stock was sold at a price of \$3.56 per share. The warrants were sold at a price of \$0.125 per share underlying each warrant, have an exercise price of \$4.09 per share and expire in July 2008.



**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 preliminary results of clinical trials;
- Anticipated regulatory filings, requirements and future clinical trials;
- Market acceptance of our products and the estimated potential size of these markets;
- Our anticipated future capital requirements and the terms of any capital financing; and
- Timing and amount of future contractual payments, product revenues and operating expenses.

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 and in our Annual Report on Form 10-K for the year ended December 31, 2002 before engaging in any transaction involving shares of our common stock. If any of these risks 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;
- Future prospects heavily dependent on results of TOCOSOL Paclitaxel;
- Dependence on third parties for funding, clinical development, manufacturing and distribution;
- Future capital requirements and uncertainty of additional funding;
- Uncertainty of U.S. or international legislative or administrative actions;
- Continued listing on the Nasdaq National Market;
- 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, protect trade secrets and avoid infringing patents held by third parties;
- Limitations on third-party reimbursement for medical and pharmaceutical products;
- Acceptance of our products by the medical community;
- Dependence on key employees;
- Potential for product liability issues and related litigation;
- Potential for claims arising from the use of hazardous materials in our business; and
- Volatility in the value of our common stock.

See "Certain Factors That May Affect Our Business and Future Results" on page 16.

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### 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
- Our current capital resources and possible sources of additional funding for future capital requirements.

### Business Overview

Sonus Pharmaceuticals is applying its novel TOCOSOL™ drug delivery technology to make therapeutic drugs safer, easier to administer and potentially more effective. Our business strategy is as follows:

- Develop proprietary, novel formulations of therapeutic drugs based on our TOCOSOL drug delivery technology. Our objective is to advance these proprietary products through Phase 1 and 2 clinical trials and then enter into collaborative agreements with larger companies to: (i) fund the pivotal clinical studies that would serve as the basis for submitting a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA); and (ii) maximize the commercial opportunity of the product.
- License our TOCOSOL drug delivery technology to other companies to enable them to improve formulations of their existing drugs or new compounds under development.
- Expand the TOCOSOL technology to other dosage forms (e.g. oral) and site-specific delivery of therapeutic drugs.

### TOCOSOL Drug Delivery Technology

Our proprietary TOCOSOL technology platform has been designed to address the formulation challenges of certain categories of therapeutic drugs. Development of drugs with our TOCOSOL technology may result in products with decreased incidences of side effects, improved dosing convenience and equivalent or better efficacy. The TOCOSOL technology uses vitamin E oil (tocopherol) to solubilize the drugs and tocopherol-based surfactants to control the size of drug delivery particles and make the product more compatible with the human body. It is this compatibility characteristic that makes our TOCOSOL technology particularly suited to injectable therapeutic drugs that are poorly soluble in water. In addition, the TOCOSOL technology may also be used in future applications to formulate oral dosage forms of hydrophobic (poorly soluble in water) and hydrophilic (water-based) drugs to improve their absorption and therapeutic utility.

### Products Under Development

*TOCOSOL Paclitaxel.* Our lead product, TOCOSOL Paclitaxel, is a novel formulation of paclitaxel, one of the world's most widely prescribed anti-cancer drugs. Paclitaxel is the active ingredient in Taxol<sup>®</sup>, which is approved in the U.S. for the treatment of breast, ovarian and non-small cell lung cancers and Kaposi's sarcoma. Our product, TOCOSOL Paclitaxel, is a ready-to-use injectable paclitaxel emulsion. TOCOSOL Paclitaxel is currently under study in Phase 2 clinical trials to evaluate safety and efficacy in multiple tumor types. We have demonstrated that TOCOSOL

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Paclitaxel can be administered to patients by a short 15 minute injection, instead of the typical three-hour infusion that is required with the currently marketed paclitaxel products.

We concluded a Phase 1 study for TOCOSOL Paclitaxel in August 2002 with a total of 37 patients. The objectives of the Phase 1 study were to estimate the maximum tolerated dose of TOCOSOL Paclitaxel in patients with advanced cancers, and to evaluate the safety of repeated doses of TOCOSOL Paclitaxel given every 3 weeks.

In the Phase 1 study, 30 of the 37 patients were treated at doses ranging from 175 mg/m<sup>2</sup> to 225 mg/m<sup>2</sup> every three weeks. The maximum tolerated dose (MTD) was estimated to be 200 mg/m<sup>2</sup> every three weeks, slightly higher than the approved dose of Taxol<sup>®</sup> at 175 mg/m<sup>2</sup> every three weeks. TOCOSOL Paclitaxel was generally well tolerated in all patients treated. All patients in the Phase 1 study had advanced cancers that were no longer responding to previous therapies or for which no standard therapy existed. Five patients with different types of cancers had objective partial responses during the course of the study, including four patients who had previously been treated with taxane-containing chemotherapy regimens. Dose-limiting toxicities included myalgia (muscle aches), fatigue, and neutropenia (low neutrophilic white cell count). No Grade 4 neuropathy (damage to the peripheral nerves) was seen at or below the estimated MTD levels.

We initiated Phase 2a studies for TOCOSOL Paclitaxel in March 2002. Our goal with the Phase 2a studies is to estimate the safety and efficacy of TOCOSOL Paclitaxel in selected tumor types. The Phase 2a studies are evaluating TOCOSOL Paclitaxel in ovarian, non-small cell lung and bladder cancers using weekly dosing of the product. These are single agent, open label studies enrolling patients who have had progressive disease despite one regimen of prior chemotherapy but who have not previously had taxane chemotherapy. Each Phase 2a study began with a dose escalation phase to estimate the best tolerated dose of TOCOSOL Paclitaxel using weekly administration. Overall, the best dose estimated for TOCOSOL Paclitaxel given weekly is 120 mg/m<sup>2</sup>.

As of June 2003, patient enrollment in the Phase 2a clinical trials has been completed. We enrolled a total of 122 patients in the ovarian, non-small cell lung and bladder cancer studies. Of the 122 patients enrolled in these studies, 98 are evaluable according to the RECIST criteria, which means that the patients have received at least 8 weekly cycles of TOCOSOL Paclitaxel and have had at least one CT scan to confirm anti-tumor responses. Among the 98 evaluable patients to date, we have seen 25 objective responses and an additional 39 patients have been reported to have stable disease. Of the objective responses, 20 are partial responses and five are complete responses. Complete response is defined as no evidence of remaining tumor, confirmed on two CT scans at least 4 weeks apart, while partial response is defined as reduction in the sums of the longest tumor dimensions of <sup>3</sup> 30% for at least 4 weeks. Stable disease is defined as no increase in any tumor size<sup>3</sup> 20%. We expect to have efficacy data on the remaining 24 patients in the next several months.

In the ovarian cancer study, 28 of 52 enrolled patients have been evaluated for anti-tumor effect. Seven of the 28 evaluable patients (25%) were reported as objective responses, including 1 complete response and 6 partial responses; 9 additional patients were reported to have stable disease. In the non-small cell lung cancer study, all 43 enrolled patients have had anti-tumor effect evaluated. Nine of the 43 evaluable patients (21%) were reported as objective responses, including 2 complete responses and 7 partial responses; 19 additional patients were reported to have stable disease. In the bladder cancer study, all 27 patients enrolled have had anti-tumor effect evaluated. Nine of the 27 evaluable patients (33%) were reported as objective responses, including 2 complete responses and 7 partial responses; 11 additional patients were reported to have stable disease.

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The Phase 2a clinical efficacy results as of June 2003 are summarized in the table below:

Cancer Type	No. Patients Enrolled	No. Patients Evaluable	Stable Disease	Objective Responses (OR)			
				Partial Response	Complete Response	Total OR	% OR
Ovarian	52	28	9	6	1	7	25%
NSCL	43	43	19	7	2	9	21%
Bladder	27	27	11	7	2	9	33%

In addition to the Phase 2a efficacy results, we are also monitoring patients for key types of adverse events such as peripheral neuropathy and transient reductions in blood cell counts. To date, the incidence of Grade 3 or Grade 4 neutropenia across all studies is 29%, which compares favorably to what has been seen following treatment with the marketed paclitaxel products in similar patient populations. The incidence of Grade 3 peripheral neuropathy is 6%, and no patients have experienced Grade 4 peripheral neuropathy, and we believe this experience compares favorably to the reported experience with Taxol. Dose reductions or delays due to toxicity of any sort are uncommon; approximately 83% of planned doses have been delivered on schedule at full dose. Paclitaxel-mediated infusion reactions, sometimes called “hypersensitivity reactions” and involving pain, flushing, shortness of breath or chest tightness, were infrequently observed following nearly 1,600 administered doses. Fewer than 17% of doses led to a reaction of any severity, and less than 1% of doses led to reactions that were of Grade 3 severity (no Grade 4 reactions occurred). Again, these frequencies compare favorably with reported rates of infusion reactions upon administration of available paclitaxel products. Investigators have reported that they believe infusion reactions with our product could be ameliorated by temporary (a few minutes) interruption of infusion, while corticosteroid premedications had no effect. Infusion reactions very rarely prevented delivery of intended doses. Overall, we are seeing excellent tolerability of TOCOSOL Paclitaxel over multiple treatment cycles, evidenced by the fact that patients typically do not need doses reduced or delayed.

The results of the Phase 2a clinical trials are preliminary at this time and may or may not be indicative of the final results upon completion of the studies.

Our near term objective is to advance the final clinical development, gain marketing approval and then maximize the commercial opportunity of TOCOSOL Paclitaxel. Based on discussions with the FDA, we have outlined a regulatory strategy for TOCOSOL Paclitaxel that gives us three pathways for getting the product approved. Our goal with the regulatory strategy is to gain the fastest possible market entry with a competitive label while in parallel pursuing opportunities to further differentiate the product. Our strategy is as follows:

- *505(b)(2)*. We will seek initial approval of TOCOSOL Paclitaxel with a 505(b)(2) NDA submission, which relies on the FDA’s previous findings of safety and effectiveness of an approved product, with additional data supporting any changes to the previously approved product (e.g., dosing regimen or formulation). The FDA’s use of this approval mechanism is designed to encourage innovation without creating duplicate work, such as conducting studies to demonstrate what is already known about a drug. We will seek to demonstrate pharmacokinetic comparability between the active amounts of paclitaxel delivered for treatment by TOCOSOL Paclitaxel and Taxol, as well as to confirm the linkage between paclitaxel pharmacokinetics and anti-tumor effect. We expect to initiate a randomized crossover clinical pharmacology study in the fourth quarter of 2003 to compare TOCOSOL Paclitaxel and Taxol, with both drugs given at 175 mg/m<sup>2</sup> every 3 weeks. If comparable pharmacokinetics of active paclitaxel can be shown between our product and Taxol, we would then conduct a single

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comparative clinical trial to assure that the efficacy provided by TOCOSOL Paclitaxel is comparable to that for which Taxol has already been approved. The NDA submission would likely follow in late 2005 or early 2006, seeking approval to market TOCOSOL Paclitaxel under the indications for which Taxol is currently approved.

- *New indication for taxanes.* Under this component of our strategy, we will pursue approval in bladder cancer, an indication for which there is currently no FDA-approved therapy, including taxanes. We plan to initiate a Phase 2b study in bladder cancer in the fourth quarter of 2003, using weekly 120 mg/m<sup>2</sup> doses of TOCOSOL Paclitaxel.
- *Taxane-approved indications.* We will conduct trials in ovarian and breast cancers, for which paclitaxel given once every three weeks is already approved, to support labeling of TOCOSOL Paclitaxel for weekly treatment of those diseases or to use higher doses of paclitaxel given every three weeks, potentially leading to greater anti-tumor efficacy. The data from these clinical trials would support supplemental new drug applications (SNDAs) following a 505(b)(2) NDA, if successful, or provide supportive data for standard NDA submissions in the event that the 505(b)(2) strategy is unsuccessful. We plan to initiate Phase 2b studies in ovarian and breast cancers by the end of 2003.

In addition to commencing the pivotal clinical trials program, we are also seeking to secure a corporate partner for TOCOSOL Paclitaxel to provide the funding for the remaining clinical development costs and also to maximize the commercial success of the product. Our objective is to enter into a corporate partner relationship for Tocosal Paclitaxel by the end of 2003. However, the consummation of the \$14.2 million private placement in July 2003, coupled with our existing cash resources (\$11.3 million at June 30), provides us additional flexibility in our ongoing negotiations with potential corporate partners and allows us to extend this objective into early 2004, if desired.

*TOCOSOL Camptothecin.* Our second product utilizing the TOCOSOL drug delivery technology is a novel injectable formulation of camptothecin, which we have named TOCOSOL Camptothecin. This formulation is based on the unmodified camptothecin molecule, which is poorly soluble and difficult to formulate for administration to humans. There are currently two marketed hydrophilic (water-based) camptothecin analogs that are based on chemical modifications to the camptothecin molecule. Irinotecan, which is marketed under the name Camptosar®, is indicated for treatment of colorectal cancer; and topotecan, which is marketed under the name Hycamptin®, is indicated for treatment of ovarian and non-small cell lung cancers. We believe the camptothecin analogs may be less active than the camptothecin parent molecule. We submitted an Investigational New Drug Exemption application (IND) to the FDA for TOCOSOL Camptothecin in late 2002. Resources permitting, we expect to begin a Phase 1 study by the end of 2003.

*Research Product Pipeline.* Consistent with our strategy to develop a pipeline of proprietary new formulations of drug candidates, we are evaluating a variety of therapeutic drug formulations utilizing our TOCOSOL drug delivery technology. We currently have formulations under investigation in areas that target cancer and other serious diseases. Our 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.

## Proprietary Technology

We consider the protection of our technology to be important to our business. In addition to seeking U.S. patent protection for many of our inventions, we are also seeking patent protection in selected other countries in order to protect our proprietary rights to inventions. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position.

Our success will depend, in part, on our ability to obtain patents, defend patents, protect trade secrets, and avoid infringing on the rights of others. To date, we have filed 23 patent applications in the U.S. pertaining to our technology and products as well as counterpart filings in Europe and key countries in Asia and Latin America. During 2002, the United States Patent and Trademark Office issued two patents to us related to TOCOSOL Paclitaxel and the TOCOSOL drug delivery technology. All other patent applications are currently in process with the United States Patent and Trademark Offices or foreign counterpart agencies, although we have received notice of allowable claims in certain applications.

## Results of Operations

As of June 30, 2003, our accumulated deficit was approximately \$45.7 million. We expect to incur additional operating losses over the next several years. Such losses have been and may continue to be principally the result of various costs associated with our discovery, research and development programs. Substantially all of our revenue to date has resulted from corporate partnerships and licensing arrangements, and interest income. Our ability to achieve a consistent, profitable level of operations depends in large part on entering into corporate partnerships for product discovery, research, development and commercialization, obtaining regulatory approvals for our products and successfully manufacturing and marketing our products once they are approved. Even if we are successful in the aforementioned activities, our operations may not be profitable. In addition, any payments under corporate partnerships and licensing arrangements are subject to significant fluctuations in both timing and amount. Therefore, our operating results for any period may fluctuate significantly and may not be comparable to the operating results for any other period.

The Company reported no revenue for the second quarter of 2003 or 2002. For the six months ended June 30, 2003 and June 30, 2002, revenue was \$25,000. Revenues for the remainder of 2003 will be dependent on our ability to enter into new collaborative agreements or licensing arrangements with third parties.

Total operating expenses for the second quarter of 2003 were \$3.1 million compared with \$3.7 million in the second quarter of 2002. The decline in operating expenses from the prior year was primarily due to lower research and development expenses (\$2.3 million in the second quarter of 2003 compared to \$2.8 million in the second quarter of 2002) as well as lower general and administrative expenses (\$802,000 in the second quarter of 2003 compared to \$861,000 in the second quarter of 2002). For the first six months of 2003, total operating expenses were \$5.5 million compared to \$6.2 million for the prior year period. The decrease primarily reflected the completion of the Phase 2 enrollment in the clinical trials for our lead product, TOCOSOL Paclitaxel, as well as cost containment in general and administrative expenses.

Net interest income was \$30,000 and \$90,000 for the three and six months ended June 30, 2003 compared with \$150,000 and \$258,000 for the same periods in 2002. The decline in net interest income for both periods was primarily due to lower levels of invested cash in the current year as well as generally lower interest rates.

## Liquidity and Capital Resources

We have historically financed operations with payments under contractual agreements with third parties and proceeds from equity financings. In July 2003, we completed a private placement that raised approximately \$13.1 million in net proceeds through the sale of 3.9 million shares of common stock.

At June 30, 2003, we had cash, cash equivalents and marketable securities of \$11.3 million compared to \$16.3 million at December 31, 2002. The decline was primarily due to the \$5.4 million net loss for the first six months of 2003. These balances are as of June 30, 2003 and do not include the \$13.1 million in net proceeds raised through the private placement of common stock in July 2003 noted above.

We expect that our cash requirements will continue to 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 including technology transfer costs related to our manufacturing and supply agreement for TOCOSOL Paclitaxel, we estimate that existing cash and marketable securities will be sufficient to meet our cash requirements through approximately mid-2005. We will need additional funding to complete the final clinical trials and obtain regulatory approval for 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 third party collaborative agreements.

Our future capital requirements depend on many factors including:

- The time and costs required to complete preclinical development and clinical trials and obtain regulatory approvals;
- The ability to attract and retain new collaborative agreement partners;
- The time and costs required to complete the technology transfer associated with manufacturing and supply agreements;
- 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 also have commitments in the form of capital leases, operating leases and leasehold financing arrangements. We have remaining contractual obligations through 2007 under our operating leases of \$2.8 million and \$344,000 under our capital lease and leasehold financing agreements. These commitments have been incorporated into our cash requirement estimates included herein.

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.

**Critical Accounting Policies and Estimates**

The preparation of the financial statements requires management to make estimates and assumptions that affect the reported amounts of liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. 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.

- *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 into agreements with third parties for research and/or clinical trial activities, costs are expensed the earlier of when amounts are due or when services are performed.



## Certain Factors That May Affect Our Business and Future Results

*If we fail to develop products, then we may never realize revenue from product commercialization.*

A key element of our business strategy is to utilize our technologies for the development and commercialization of products that utilize our drug delivery technology. The initial application of our drug delivery technology, TOCOSOL, is a novel approach to the formulation of water insoluble compounds for therapeutic applications. Significant expenditures in additional research and development, clinical testing, regulatory, manufacturing, and sales and marketing activities will be necessary in order for us to demonstrate the efficacy of our products, or commercialize any products developed with our technology. There can be no assurance that TOCOSOL Paclitaxel or any of our other current products under development or any future products will be safe or efficacious.

Even if we are successful in developing our products, there is no assurance that such products will receive regulatory approval or that a commercially viable market will develop. While it is our strategy to develop additional products under our drug delivery technology by entering into feasibility study agreements with companies who own active compounds, there can be no assurance that we will enter into any feasibility studies. Moreover, there can be no assurance that these feasibility studies will result in development or license agreements. Without feasibility studies or development or license agreements, we may need to scale back or terminate our efforts to develop other products using our drug delivery technology.

*We have a history of operating losses which we expect will continue and we may never become profitable.*

We have experienced significant accumulated losses since our inception, and are expected to incur net losses for the foreseeable future. These losses have resulted primarily from expenses associated with our research and development activities, including nonclinical and clinical trials, and general and administrative expenses. As of June 30, 2003, our accumulated deficit totaled \$45.7 million. We anticipate that our operating losses will continue as we further invest in research and development for our products. We will not generate any product revenues unless and until we receive regulatory approval, which will not occur in the near future. Even if we generate significant product revenues, there can be no assurance that we will be able to achieve or sustain profitability. Our results of operations have varied and will continue to vary significantly and depend on, among other factors:

- The timing and costs of clinical trials and regulatory approvals;
- Entering into new collaborative or product license agreements;
- The timing and costs of technology transfer associated with manufacturing and supply agreements;
- The timing of payments, if any, under collaborative partner agreements; and
- Costs related to obtaining, defending and enforcing patents.

*Governmental regulatory requirements are lengthy and expensive and failure to obtain necessary approvals will prevent us or our partners from commercializing a product.*

We are subject to uncertain governmental regulatory requirements and a lengthy approval process for our products prior to any commercial sales of our products. The development and commercial use of our products are regulated by the U.S. Food and Drug Administration, or FDA, the European

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Medicines Evaluation Agency, or EMEA, and comparable regulatory agencies in other countries. The regulatory approval process for new products is lengthy and expensive. Before we can file an application with the FDA and comparable international agencies, the product candidate must undergo extensive testing, including animal studies and human clinical trials that can take many years and require substantial expenditures. Data obtained from such testing may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in regulatory policy for product approval may cause additional costs in our efforts to secure necessary approvals.

Our drug delivery products are subject to significant uncertainty because they are in the early stages of development and are subject to regulatory approval. We filed an Investigational New Drug Exemption application, or IND, with the FDA for TOCOSOL Paclitaxel in September 2000 and completed the Phase 1 clinical study for this product in August 2002. In March 2002, we initiated the first four Phase 2a clinical trials for TOCOSOL Paclitaxel. Included in this first group of Phase 2a clinical trials was a trial in colorectal cancer that was terminated in 2002 due to insufficient indications of efficacy. As of June 30, 2003, we have completed enrollment in the current Phase 2 program. There can be no assurance that current and future clinical studies will demonstrate that TOCOSOL Paclitaxel will be safe or efficacious, that the required comparable pharmacokinetic profile to Taxol will be proven in connection with our 505(b)(2) strategy, or that we will file a New Drug Application. We are also currently engaged in the development of a formulation of camptothecin using our TOCOSOL drug delivery technology. We filed an IND for TOCOSOL Camptothecin with the FDA in late 2002 and, resources permitting, expect to begin a Phase 1 study by the end of 2003. The results of pre-clinical and clinical testing of our products are uncertain and regulatory approval of our products may take longer or be more expensive than anticipated, which could have a material adverse effect on our business, financial condition and results of operations. We cannot predict if or when any of our products under development will be commercialized.

*Our future prospects are heavily dependent on the results of TOCOSOL Paclitaxel.*

Most of our attention and resources are directed to the development of TOCOSOL Paclitaxel. If TOCOSOL Paclitaxel is ultimately ineffective in treating cancer, does not receive the necessary regulatory approvals or does not obtain commercial acceptance, we will be materially adversely affected.

*We depend on third parties for funding, clinical development, manufacturing and distribution.*

We are dependent, and may in the future be dependent, on third parties for funding or performance of a variety of key activities including research, clinical development, manufacturing, marketing, sales and distribution of our products. Our current business strategy is to enter into agreements with third parties both to license rights to our potential products and to develop and commercialize new products. We currently do not have any arrangements with third parties in place, which will provide any funding to the Company. If we are unable to establish these arrangements with third parties, if they are terminated or the collaborations are not successful, we will be required to identify alternative partners to fund or perform research, clinical development, manufacturing, marketing, sales and/or distribution, which could have a material adverse effect on our business, financial condition and results of operations. Our success depends in part upon the performance by these collaborators of their responsibilities under these arrangements. We have no control over the resources that any potential partner may devote to the development and commercialization of products under these collaborations and our partners may fail to conduct their collaborative activities successfully or in a timely manner. In connection with the manufacturing scale-up project for TOCOSOL Paclitaxel, we signed a manufacturing agreement with SICOR Pharmaceuticals, Inc. in July 2002 for the manufacturing of clinical and commercial supplies of the product.

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*We will need additional capital in the future, and if it is not available on terms acceptable to us, or at all, we may need to scale back our development and commercialization activities.*

Our development efforts to date have consumed and will continue to require substantial amounts of cash, and we have generated only limited revenues from payments received from our contractual agreements and from the assignment of substantially all of our ultrasound contrast intellectual property. 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 approximately mid-2005. However, we will need substantial additional capital to complete the development of TOCOSOL Paclitaxel as well as other product candidates and to meet our other cash requirements in the future. Our future capital requirements depend on many factors including:

- The time and costs required to complete preclinical development and clinical trials and obtain regulatory approvals;
- The ability to attract and retain new collaborative agreement partners;
- The time and costs required to complete the technology transfer associated with manufacturing and supply agreements;
- 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.

Any future equity financing, if available, may result in substantial dilution to existing stockholders, and debt financing, if available, may include restrictive covenants. If we are unable to raise additional financing, we will have to substantially reduce our expenditures, scale back the development of our products and new product research and development, or license to others products that we otherwise would seek to commercialize ourselves, which could seriously harm our business, and explore other strategic alternatives.

*Future U.S. or international legislative or administrative actions also could prevent or delay regulatory approval of our products.*

Even if regulatory approvals are obtained, they may include significant limitations on the indicated uses for which a product may be marketed. A marketed product also is subject to continual FDA, EMEA and other regulatory agency review and regulation. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions. In addition, if marketing approval is obtained, the FDA, EMEA or other regulatory agency may require post-marketing testing and surveillance programs to monitor the product's efficacy and side effects. Results of these post-marketing programs may prevent or limit the further marketing of a product.

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*Failure to satisfy Nasdaq National Market Listing requirements may result in our common stock being delisted from The Nasdaq National Market.*

Our common stock is currently listed on The Nasdaq National Market under the symbol "SNUS." For continued inclusion on The Nasdaq National Market, we must maintain among other requirements stockholders' equity of at least \$10.0 million, a minimum bid price of \$1.00 per share and a market value of our public float of at least \$5.0 million; or market capitalization of at least \$50 million, a minimum bid price of \$3.00 per share and a market value of our public float of at least \$15.0 million. As of June 30, 2003, we had stockholders' equity of \$10.4 million. In July 2003, we raised \$13.1 million of additional equity in a private placement transaction. In the event that we fail to satisfy the listing standards on a continuous basis, our common stock may be removed from listing on The Nasdaq National Market. If our common stock were delisted from The Nasdaq National Market, our common stock may be transferred to the Nasdaq SmallCap Market if we satisfy the listing criteria for the Nasdaq SmallCap Market or trading of our common stock, if any, may be conducted in the over-the-counter market in the so-called "pink sheets" or, if available, the NASD's "Electronic Bulletin Board." In addition, delisting from Nasdaq may subject our common stock to so-called "penny stock" rules. These rules impose additional sales practice and market making requirements on broker-dealers who sell and/or make a market in such securities. Consequently, broker-dealers may be less willing or able to sell and/or make a market in our common stock. Additionally, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, our common stock. As a result of a delisting, it may become more difficult for us to raise funds through the sale of our securities.

*The development of pharmaceutical products in general and the development of paclitaxel reformulations in particular is extremely competitive, and if we fail to compete effectively, it would negatively impact our business.*

Competition in the development of pharmaceutical products is intense and expected to increase. We also believe that other medical and pharmaceutical companies will compete with us in the areas of research and development, acquisition of products and technology licenses, and the manufacturing and marketing of our products. Success of products in these fields will be based primarily on:

- Efficacy;
- Safety;
- Price;
- Ease of administration;
- Breadth of approved indications; and
- Physician, healthcare payer and patient acceptance.

Several other companies are developing paclitaxel reformulations with a goal of delivering a more effective and tolerable therapy than the approved paclitaxel products. Some of these products are further in development than TOCOSOL Paclitaxel and may achieve regulatory approval before our product. In addition, Aventis has a docetaxel product, Taxotere®, which is similar to paclitaxel and is marketed for the treatment of breast and non-small cell lung cancers. As a result of the increased competition, the price for paclitaxel products has been under pressure.

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Many of our competitors and potential competitors, including large pharmaceutical, chemical and biotechnology concerns and universities and other research institutions, have substantially greater financial, technical and human resources than we do and have substantially greater experience in developing products, obtaining regulatory approvals and marketing and manufacturing medical products. Accordingly, these competitors may succeed in obtaining FDA approval for their products more rapidly than us. In addition, other technologies or products may be developed that have an entirely different approach that would render our technology and products noncompetitive or obsolete. If we fail to compete effectively, it would have a material adverse effect on our business, financial condition and results of operations.

*We rely on third party suppliers and manufacturers to produce products that we develop and failure to retain such suppliers and manufacturers would adversely impact our ability to commercialize our products.*

We currently rely on third parties to supply the chemical ingredients necessary for our drug delivery products. Currently, Indena SpA is our primary supplier of paclitaxel, the main ingredient in TOCOSOL Paclitaxel. The chemical ingredients for our products are manufactured by a limited number of vendors. The inability of these vendors to supply medical-grade materials to us could delay the manufacturing of, or cause us to cease the manufacturing of our products. We also rely on third parties to manufacture our products for research and development and clinical trials. SICOR Pharmaceuticals, Inc. is our primary manufacturer of TOCOSOL Paclitaxel for clinical studies and has also agreed to manufacture TOCOSOL Paclitaxel for commercialization. We previously manufactured clinical supplies of TOCOSOL Paclitaxel at other GMP certified contract laboratories. Suppliers and manufacturers of our products must operate under GMP regulations, as required by the FDA, and there are a limited number of contract manufacturers that operate under GMP regulations. Our reliance on independent manufacturers involves a number of other risks, including the absence of adequate capacity, the unavailability of, or interruptions in, access to necessary manufacturing processes and reduced control over delivery schedules. If our manufacturers are unable or unwilling to continue manufacturing our products in required volumes or have problems with commercial scale-up, we will have to identify acceptable alternative manufacturers. The use of a new manufacturer may cause significant interruptions in supply if the new manufacturer has difficulty manufacturing products to our specifications. Further, the introduction of a new manufacturer may increase the variation in the quality of our products.

*If we fail to secure adequate intellectual property protection or become involved in an intellectual property dispute, it could significantly harm our financial results and ability to compete.*

Our success will depend, in part, on our ability to obtain and defend patents and protect trade secrets. To date, we have two United States patents issued and 23 patent applications filed in the United States pertaining to our TOCOSOL drug delivery technology as well as counterpart filings in Europe and key countries in Asia and Latin America. The patent position of medical and pharmaceutical companies is highly uncertain and involves complex legal and factual questions. There can be no assurance that any claims which are included in pending or future patent applications will be issued, that any issued patents will provide us with competitive advantages or will not be challenged by third parties, or that the existing or future patents of third parties will not have an adverse effect on our ability to commercialize our products. Furthermore, there can be no assurance that other companies will not independently develop similar products, duplicate any of our products or design around patents that may be issued to us. Litigation may be necessary to enforce any patents issued to us or to determine the scope and validity of others' proprietary rights in court or administrative proceedings. Any litigation or administrative proceeding could result in substantial costs to us and distraction of our management. An adverse ruling in any litigation or administrative

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proceeding could have a material adverse effect on our business, financial condition and results of operations.

*Our commercial success will depend in part on not infringing patents issued to competitors.*

There can be no assurance that patents belonging to competitors will not require us to alter our products or processes, pay licensing fees or cease development of our current or future products. Any litigation regarding infringement could result in substantial costs to us and distraction of our management, and any adverse ruling in any litigation could have a material adverse effect on our business, financial condition and results of operations. Further, there can be no assurance that we will be able to license other technology that we may require at a reasonable cost or at all. Failure by us to obtain a license to any technology that we may require to commercialize our products would have a material adverse effect on our business, financial condition and results of operations. In addition, to determine the priority of inventions and the ultimate ownership of patents, we may participate in interference, reissue or re-examination proceedings conducted by the U.S. Patent and Trademark Office or in proceedings before international agencies with respect to any of our existing patents or patent applications or any future patents or applications, any of which could result in loss of ownership of existing, issued patents, substantial costs to us and distraction of our management.

*Reimbursement procedures and future healthcare reform measures are uncertain and may adversely impact our ability to successfully sell pharmaceutical products.*

Our ability to successfully sell any pharmaceutical products will depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse patients for the costs of future pharmaceutical products and related treatments. In the United States, government and other third-party payers have sought to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products approved for marketing by the FDA. In some cases, these payers may refuse to provide any coverage for uses of approved products to treat medical conditions even though the FDA has granted marketing approval. Healthcare reform may increase these cost containment efforts. We believe that managed care organizations may seek to restrict the use of new products, delay authorization to use new products or limit coverage and the level of reimbursement for new products. Internationally, where national healthcare systems are prevalent, little if any funding may be available for new products, and cost containment and cost reduction efforts can be more pronounced than in the United States.

*If our products are not accepted by the medical community our business will suffer.*

Commercial sales of our proposed products will substantially depend upon the products' efficacy and on their acceptance by the medical community. Widespread acceptance of our products will require educating the medical community as to the benefits and reliability of the products. Our proposed products may not be accepted, and, even if accepted, we are unable to estimate the length of time it would take to gain such acceptance.

*If we lose our key personnel or are unable to attract and retain qualified scientific and management personnel, we may be unable to become profitable.*

We are highly dependent on our key executives. The loss of any of these key executives or the inability to recruit and retain qualified scientific personnel to perform research and development and qualified management personnel could have a material adverse effect on our business, financial condition and results of operations. We do not have employment contracts with any of our key personnel and we do not maintain insurance policies that would compensate us for the loss of their services. There can be no assurance that we will be able to attract and retain such personnel on

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acceptable terms, if at all, given the competition for experienced scientists and other personnel among numerous medical and pharmaceutical companies, universities and research institutions.

*The businesses in which we engage have a risk of product liability, and in the event of a successful suit against us, our business could be severely harmed.*

The testing, marketing and sale of pharmaceutical products entails a risk of product liability claims by consumers and others. While we currently maintain product liability insurance, which we believe to be adequate for current applications of our products, such insurance may not continue to be available at a reasonable cost or may not be sufficient to fully cover any potential claims. In the event of a successful suit against us, the lack or insufficiency of insurance coverage could have a material adverse effect on our business and financial condition.

*Since we use hazardous materials in our business, we may be subject to claims relating to improper handling, storage or disposal of these materials.*

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

*Market volatility may affect our stock price and the value of an investment in our common stock may be subject to sudden decreases.*

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, preclinical and clinical trial results, market perception of the prospects for biotechnology companies as an industry sector and general market and economic conditions, some of which are beyond our control. Factors such as fluctuations in our financial and operating results, changes in government regulations affecting product approvals, reimbursement or other aspects of our or our competitors' businesses, FDA review of our product development activities, the results of preclinical studies and clinical trials, announcements of technological innovations or new commercial products by us or our competitors, developments concerning key personnel and our intellectual property rights, significant collaborations or strategic alliances and publicity regarding actual or potential performance of products under development by us or our competitors could also cause the market price of our common stock to fluctuate substantially. In addition, the stock market has from time to time experienced extreme price and volume fluctuations. These broad market fluctuations may lower the market price of our common stock. Moreover, during periods of stock market price volatility, share prices of many biotechnology companies have often fluctuated in a manner not necessarily related to the companies' operating performance. Also, biotechnology stocks may be volatile even during periods of relative market stability. Accordingly, our common stock may be subject to greater price volatility than the stock market as a whole.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

The market risk inherent in our marketable securities 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 June 30, 2003, 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.

**Item 4. Controls and Procedures**

An evaluation as of the end of the period covered by this report was carried out, under the supervision and participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information required to be included in our periodic SEC filings.

**Part II. Other Information**

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

In July 2003, Sonus sold 3,930,071 shares of its common stock for a purchase price of \$3.56 per share and warrants to purchase up to 1,965,031 shares of its common stock for a purchase price per warrant of \$.125 per share underlying each warrant. The warrants are exercisable at any time prior to July 2008 at an exercise price of \$4.09 per share. The aggregate purchase price of the common stock and warrants to purchase common stock was approximately \$14.2 million, resulting in net proceeds to Sonus of approximately \$13.1 million. Sonus and the investors concurrently entered into a Registration Rights Agreement under which Sonus has agreed to file a registration statement under the Securities Act of 1933, as amended, to register for resale all of the shares of common stock and shares of common stock issuable upon exercise of the warrants sold in the offering. The shares of common stock and warrants to purchase common stock were sold to new and current institutional and accredited investors in conformity with rule 506 under Regulation D and under Section 4(2) of the Securities Act. Each of the investors represented such investor's intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the instruments representing the common stock and warrants issued by Sonus. The offering was conducted without any general solicitation or advertising.

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

Information regarding matters submitted to a vote of security holders at our annual meeting of stockholders held on April 30, 2003, is set forth in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2003.



**Item 6. Exhibits and Reports on Form 8-K**

**(a) Exhibits**

10.53	First Amendment dated May 5, 2003 to Supply Agreement dated January 22, 2002 between Indena SpA and Sonus Pharmaceuticals, Inc.
10.54	Change in Control Agreement for Michael B. Stewart.
31.1	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**(b) Reports on Form 8-K**

The Company filed the following report on Form 8-K during the quarter ended June 30, 2003:

1. The Registrant filed a report on Form 8-K on April 22, 2003 in connection with the Company's first quarter conference call.

**Items 1, 3 and 5 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: August 13, 2003

By: /s/ Richard J. Klein

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Richard J. Klein  
Chief Financial Officer  
(Principal Financial and Accounting Officer)

FIRST AMENDMENT TO  
SUPPLY AGREEMENT

This First Amendment to Supply Agreement (the "Amendment") is made as of this day of March 31, 2003, by and between Sonus Pharmaceuticals, Inc., a Delaware corporation ("Sonus"), and Indena SpA, a company organized and existing under the laws of Italy ("Indena").

RECITALS:

A. Indena and Sonus are parties to that certain Supply Agreement dated January 22, 2002 (the "Agreement"), pursuant to which Indena has agreed to supply Sonus with medical grade paclitaxel.

B. The Agreement sets forth the date on which Indena will begin regular supplies of the Product.

C. Pursuant to Section 5.3 of the Agreement, Sonus and Indena desire to revise the date for the beginning of regular supplies of the Product.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. INITIAL SUPPLIES. Section 3 of the Agreement is hereby amended and restated to read in full as follows:

"3.1 Until such time as Supplier begins the Further Supplies in accordance with Section 4, Supplier undertakes to supply and Purchaser undertakes to purchase up to 2000 grams of Product per calendar year, prorated for any portion of a year, to be used by Purchaser to manufacture the Finished Product (the "Initial Supplies"). Notwithstanding the foregoing, in the event that Purchaser's clinical trials require additional Product, upon thirty (30) days advance written notice, Supplier undertakes to increase the Initial Supplies and supply such additional Product as Purchaser may request, provided, that if the aggregate amounts requested exceed 1,000 grams during any calendar quarter, Supplier shall use commercial reasonable efforts to supply such excess amounts, but shall not be obligated to fulfill such requests with respect to such excess.

3.2 Orders for each lot of Initial Supplies shall be placed with Supplier at least 90 days before the requested date of supply."

2. REGULAR SUPPLIES. Section 4 of the Agreement is hereby amended and restated to read in full as follows:

"Regular supplies of Product (the "Further Supplies") shall begin within thirty (30) days after the date on which Sonus receives unconditional FDA Approval, or such other date as the parties may agree in writing, as provided in Section 5 of the Agreement."

3. FORECASTS AND ORDERS.

3.1 The first paragraph of Section 5.1 of the Agreement is hereby amended and restated to read in full as follows:

"5.1 Promptly following receipt of unconditional FDA Approval, Purchaser shall submit to Supplier an estimated forecast of the quantities of Product that Purchaser expects to order during the remainder of the calendar year in which unconditional FDA Approval was obtained (the "Partial Year"). By October 31 of each year during the term hereof, starting with the year in which unconditional FDA Approval is obtained, Purchaser shall submit to Supplier an estimated rolling forecast of the quantities of Product that Purchaser expects to order during the two following years, provided, that if unconditional FDA Approval is obtained after October 31 of such year, the estimated rolling forecast shall be delivered as soon as practicable following unconditional FDA Approval, but in no event later than thirty days following unconditional FDA Approval. The forecast for the Partial Year shall be binding and considered a firm purchase commitment.

3.2 Section 5.2 of the Agreement is hereby amended and restated to read in full as follows:

"5.2 By no later than two weeks following submission by Purchaser of a firm purchase order for Product, Supplier will confirm in writing to Purchaser the receipt and acceptance of such firm order. Failure to confirm such firm order in writing within such time period or full or partial shipment of any such order shall be deemed acceptance of such firm order in full."

3.3 Section 5.3 of the Agreement is hereby amended and restated to read in full as follows:

"In the event that the parties agree on a date other than a date within thirty (30) days following FDA Approval for the beginning of regular supplies, the dates set out in the preceding Sections may be revised by mutual agreement."

4. DEFINITIONS. Unless otherwise defined herein, capitalized terms used in this Amendment shall have the same meanings ascribed to them in the Agreement.

5. ENTIRE AGREEMENT. The Agreement, as amended by this Amendment, constitutes the full and complete agreement between the parties hereto regarding the subject matter of the Agreement and shall supersede all prior understanding or agreements, if any, whether written or oral, concerning the subject matter of the Agreement, as amended.

6. FORCE AND EFFECT. Except as modified by this Amendment, the terms and provisions of the Agreement are hereby ratified and confirmed and are and shall remain in full force and effect.

7. COUNTERPARTS. This Amendment may be executed in one or more counterparts, all of which together shall constitute one instrument.

8. EXECUTION. This Amendment may be executed by facsimile signatures and such signature will be deemed binding for all purposes of this Amendment, without delivery of an original signature being required.

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IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the date first written above.

SONUS PHARMACEUTICALS, INC.

By: /s/ Michael A. Martino  
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Name: Michael A. Martino  
Title: President and Chief Executive Officer

INDENA, SpA

By: /s/ G.P. Forni  
-----

Name: G.P. Forni  
Title: Sr. Vice President Mktg and Business  
Development

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SONUS PHARMACEUTICALS, INC.  
22026 20TH AVENUE, SUITE 201  
BOTHELL, WASHINGTON 98021

May 1, 2003

Michael B. Stewart, M.D.  
c/o Sonus Pharmaceuticals, Inc.  
22026 20th Avenue SE  
Bothell, Washington 98021

Re: Change In Control Agreement

Dear Michael:

In consideration of your continued employment with Sonus Pharmaceuticals, Inc., a Delaware corporation (the "Company"), this letter agreement (the "Agreement") sets forth the compensation and benefits you will be entitled to receive in the event your employment terminates in connection with a change in control of the Company under the conditions described below. This Agreement takes effect on the date set forth above.

1. TERMINATION OF EMPLOYMENT.

1.1. During the term of this Agreement, you will be entitled to the benefits provided in Section 2 of this Agreement in the event (A) a Change in Control has occurred; and (B) (i) you terminate your employment with the Company for Good Reason within 12 months following the Change of Control, or (ii) the Company terminates your employment for reasons other than Cause, Disability, or your death within 12 months following the Change of Control, provided you fulfill your obligations under this Agreement.

1.2. For purposes of this Agreement, the term "Change in Control" shall mean (i) a sale of fifty percent (50%) or more of the outstanding shares of common stock of the Company; (ii) a sale of all or substantially all of the assets of the Company, or (iii) a merger, consolidation or reorganization whereby the stockholders of the Company immediately prior to the consummation of such merger, consolidation or reorganization own less than fifty percent (50%) of the outstanding shares of common stock immediately following the consummation of the merger, consolidation or reorganization.

1.3. For purposes of this Agreement, the term "Good Reason" shall mean any of the following, if done without your consent:

1.3.1. A substantial diminution in your duties and responsibilities to a level substantially beneath that of your duties and responsibilities at the outset of your employment under

Michael B. Stewart, M.D.  
May 1, 2003  
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this Agreement other than actions that are not taken in bad faith and are remedied by the Company within thirty days after written notice by you;

1.3.2. A reduction by the Company in your current annual base salary unless such reduction is attributable to an across the board salary reduction for all of management personnel of the Company and then only if the percentage of your reduction is (i) not greater than 20%, and (ii) no greater than that of the other management personnel;

1.3.3. The Company requires the relocation of your base of employment outside the Seattle, Washington metropolitan area;

1.3.4. A material breach by the Company of any of the terms and provisions of this Agreement, which is not cured within 30 days of written notice by you of such breach; or

1.3.5. the failure of the Company to obtain a satisfactory agreement from any successor in a Change of Control to assume and agree to perform this Agreement, as contemplated in Section 6 hereof.

1.4. For purposes of this Agreement, the term "Cause" shall mean any of the following: (i) your willful and continued failure or refusal to perform your duties with the Company; (b) your willfully engaging in gross misconduct injurious to the Company; (c) your being convicted or pleading guilty or nolo contendere to any misdemeanor involving moral turpitude or to any felony; (d) your having materially breached any provision of this Agreement, or any agreement concerning confidentiality or ownership of inventions with the Company and failed to cure such breach to the reasonable satisfaction of the Company within thirty (30) days following written notice of breach, if such cure

is possible.

1.5. For purposes of this Agreement, the term "Disability" shall mean your inability to perform the essential functions of your position due to any physical or mental illness even with reasonable accommodation to the extent required by law, for any period of six months in the aggregate during any twelve months, provided the Company has given you a written demand to return to your full time duties.

1.6 Any termination of employment by you or by the Company pursuant to this Agreement shall be communicated by written Notice of Termination indicating the termination provision in this Agreement relied upon, if any. For purposes of this Agreement, the "Date of Termination" shall mean the date specified in the Notice of Termination which shall not be earlier than ten (10) business days after the date on the Notice of Termination is given.

## 2. COMPENSATION UPON TERMINATION.

2.1. If your employment shall be terminated and you are entitled to benefits under Section 1 of this Agreement then, except as provided in Subsection 2.2, you shall receive the following benefits:

2.1.1. the Company shall pay to you in a lump sum within ten days following the Date of Termination (a) your base salary unpaid through the Date of Termination at the rate in effect

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as of the time of Notice of Termination and (b) an amount equal to the value as of the Date of Termination of the deferred portion of any bonus which has been declared but is unpaid under any incentive compensation plan or program of the Company then in effect;

2.1.2. the Company shall pay to you as severance pay in a lump sum within thirty days following the Date of Termination an amount equal to your highest annual base salary in effect any time during the twelve (12) month period prior to the Date of Termination; and

2.1.3. the Company shall maintain in full force and effect, for the continued benefit of you for one year after the Date of Termination, or, if sooner, until you are employed in a full-time capacity by another employer, all non-cash health and welfare plans and programs (excluding 401(k) or any employee bonus plans and programs or retirement plans or programs) in which you participated immediately prior to the Date of Termination provided that your continued participation is permissible under the general terms and provisions of such plans and programs. In the event that your participation in any such plan or program is barred, the Company shall arrange to provide you with benefits substantially similar to those which you are entitled to receive under such plans and programs at no cost to you. At the end of the period of coverage, you shall have the option to have assigned to you at no cost and with no apportionment of prepaid premiums, any assignable insurance policy owned by the Company and relating to specifically to you.

2.2. Notwithstanding Section 1, the respective obligations of, and benefits afforded to, the Company and you as provided in this Section 2, shall survive termination of this Agreement.

2.3. No compensation or benefits shall be due under this Agreement in the event your employment is terminated by you or the Company in circumstances other than those described in Section 1.1, including but not limited to a termination by you for any reason other than Good Reason, a termination by the Company for Cause, disability, or death, or any termination that does not occur within twelve months following a Change in Control.

2.4. To the extent that any or all of the payments and benefits provided for in this Agreement constitute "parachute payments" within the meaning of Section 280G of the Internal Revenue Code (the "Code") and, but for this Section 2.4 would be subject to the excise tax imposed by Section 4999 of the Code, the aggregate amount of such payments and benefits shall be reduced such that the present value thereof (as determined under the Code and applicable regulations) is equal to 2.99 times the Executive's "base amount" (as defined in the Code). The determination of any reduction of any payment or benefits under Section 2 pursuant to the foregoing provision shall be made by a nationally recognized public accounting firm chosen by the Company in good faith, and such determination shall be conclusive and binding on the Company and you.

## 3. OTHER BENEFITS.

In the event you are entitled to any compensation or benefits under this Agreement, you shall not be entitled to any other severance compensation or benefits under any other policy or agreement with the Company.

4. PROPRIETARY INFORMATION AND UNFAIR COMPETITION.

4.1 You acknowledge that in the course of your employment with the Company, you will be entrusted with access to extensive confidential information of the Company concerning its products and service, methods of manufacture, research and development, know-how, patents, copyrights, trademarks, and other proprietary data, as well as the identity, needs, and preferences of its customers and prospects, all of which the Company considers its legally protected trade secrets and intellectual property. You further acknowledge the highly competitive nature of the business of the Company, and the fact that unauthorized disclosure or use of such trade secrets and intellectual property would be inevitable if you were to compete with the Company or solicit competing business from its prospects and customers. You therefore agree as follows:

4.2 Commencing on the Date of Termination, and ending one year thereafter (the "Non-Compete Period"), you will not provide goods or services to or become an employee, owner (except for passive investments of not more than three percent of the outstanding shares of, or any other equity interest in, any company or entity listed or traded on a national securities exchange or in an over-the-counter securities market), officer, agent, consultant, advisor or director of any firm or person in any geographic area which competes in the "Business". For purposes of this Agreement, the term "Business" shall mean the research, design, development, manufacture, sale or distribution of drug delivery products using the Company's Tococol(TM) technology.

4.3 During the Non-Compete Period, you will not directly or indirectly induce any employee of the Company or any of its affiliates to engage in any activity in which you are prohibited from engaging by paragraph 5.1 above, or to terminate such employee's employment with the Company, or any of its affiliates, and will not directly or indirectly employ or offer employment to any person who was employed by the Company or any of its affiliates unless such person shall cease to be employed by the Company or any of its affiliates for a period of at least 12 months; provided, however, that this provision shall not apply to any person who is no longer an employee of the Company or any of its affiliates as of a result of actions taken by the Company or its affiliates.

4.4 During the Non-Compete Period, you will refrain from making any statement which has the effect of demeaning the name or the business reputation of the Company or its subsidiaries or affiliates, or any officer or employee thereof, or which materially adversely effects the best interests (economic or otherwise) of the Company, its subsidiaries or affiliates.

4.5. It is expressly understood and agreed that although you and the Company consider the restrictions contained in this Section 5 to be reasonable, if a final judicial determination is made by a court of jurisdiction that the time or territory or any other restriction contained in this Agreement is an unenforceable restriction against you, provisions of this Agreement shall not be rendered void, but shall be deemed amended to apply to such maximum time and territory and to such maximum extent as such court may judicially determine or indicate to be enforceable. Alternatively, if any court of competent jurisdiction finds that any restriction contained in this Agreement is unenforceable, and such restriction cannot be amended so as to make it enforceable, such finding shall not effect the enforceability of any of the other restriction contained herein.

5. MISCELLANEOUS.

Any payment required under this Agreement shall be subject to all requirements of the law with regard to withholding, filing, making of reports and the like, and the Company shall use its commercially reasonable best efforts to satisfy promptly all such requirements. No provisions of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in a writing signed by both parties. The validity, interpretation, construction and performance of this Agreement shall be governed by the law of the State of Delaware.

6. SUCCESSORS AND ASSIGNMENT.

This agreement and all of your rights thereunder shall inure to the benefit of and be enforceable by your personal or legal representatives, executors, administrators, successors, heirs, distributees, devisees and legatees. Except as expressly provided in this Agreement, this Agreement is personal to you and may not be assigned to you. If you should die while any amounts would still be payable to you hereunder if you had continued to live, all such amounts, unless otherwise provided herein, shall be paid in accordance

with the terms of this Agreement to your devisee, legatee, or other designee or, if there be no such designee, to your estate. This Agreement shall be binding upon any successor to the Company (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company.

7. TERM OF AGREEMENT.

This Agreement shall commence as of the date of this Agreement and shall terminate on the earliest of (i) the termination of your employment by the Company for Cause, Disability or death; (ii) your termination of employment other than for Good Reason or (iii) your reaching age 65.

8. NO GUARANTEE OF CONTINUED EMPLOYMENT.

This Agreement is intended solely to provide you with certain compensation and benefits in the event your employment terminates in the circumstances described in Section 1.1. Nothing in this Agreement constitutes or implies any specific term of employment. You acknowledge and agree that your employment with the Company can be terminated by you or the Company at any time with or without cause or prior warning. Nothing in this Agreement limits or supercedes any other agreements between you and the Company concerning confidentiality or ownership of intellectual property.

9. MEDIATION

In the event that the Company terminates you for Cause and you dispute its right to do so or you claim that you are entitled to terminate your employment for Good Reason and the Company disputes your right to do so, a mediator acceptable to you and the Company will be appointed within ten (10) days to assist in reaching a mutually satisfactory resolution but will have no authority to issue a binding decision. Such mediation must be concluded within 60 days of the date of termination or claim to termination. Should such mediation fail to reach an acceptable conclusion and you are successful in any litigation or settlement that issues from such dispute, you shall be entitled to receive from the Company all of the expenses incurred by you in connection with any such dispute including reasonable attorney's fees.

Michael B. Stewart, M.D.  
May 1, 2003  
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If this Agreement is acceptable to you, kindly sign and return to the Company the enclosed copy of this letter.

Sincerely,

Sonus Pharmaceuticals, Inc.

/s/ Michael A. Martino

-----  
Micheal A. Martino  
President and Chief Executive Officer

AGREED AND ACCEPTED:

/s/ Michael B. Stewart M.D.  
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Michael B. Stewart, M.D.

Dated: May 15, 2003



CERTIFICATION PURSUANT TO RULE 13a-14 AND RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934

I, Michael A. Martino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sonus Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2003

/s/ Michael A. Martino  
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Michael A. Martino  
President and Chief Executive Officer

CERTIFICATION PURSUANT TO RULE 13a-14 AND RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934

I, Richard J. Klein, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sonus Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 13, 2003

/s/ Richard J. Klein  
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Richard J. Klein  
Chief Financial Officer

SECTION 906 CERTIFICATION OF PERIODIC REPORT

I, Michael A. Martino, President and Chief Executive Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2003 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 13, 2003

/s/ Michael A. Martino

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Michael A. Martino  
President and Chief Executive Officer

SECTION 906 CERTIFICATION OF PERIODIC REPORT

I, Richard J. Klein, Chief Financial Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2003 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 13, 2003

/s/ Richard J. Klein  
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Richard J. Klein  
Chief Financial Officer