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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 September 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** | **95-4343413** |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (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 November 6, 2003 |
|---|---|
| Common Stock, $.001 par value | 17,938,333 |

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**Part I. Financial Information**

**Item 1. Financial Statements**

**Sonus Pharmaceuticals, Inc.**

**Balance Sheets**

| | September 30, 2003 | December 31, 2002 |
|---|---|---|
| | (unaudited) | |
| **Assets** | | |
| Current assets: | | |
| Cash, cash equivalents and marketable securities | $ 22,149,054 | $ 16,334,004 |
| Other current assets | 176,154 | 289,909 |
| Total current assets | 22,325,208 | 16,623,913 |
| Property and equipment, net | 1,567,072 | 1,310,390 |
| Total assets | $ 23,892,280 | $ 17,934,303 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | $ 2,436,120 | $ 1,800,786 |
| Current portion of lease obligations | 147,803 | 137,602 |
| Total current liabilities | 2,583,923 | 1,938,388 |
| Lease obligations, less current portion | 159,824 | 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; 17,708,020 and 13,691,547 shares issued and outstanding at September 30, 2003 and December 31, 2002, respectively | 69,319,162 | 56,010,950 |
| Accumulated deficit | (48,173,956) | (40,312,665) |
| Accumulated other comprehensive income | 3,327 | 25,643 |
| Total stockholders' equity | 21,148,533 | 15,723,928 |
| Total liabilities and stockholders' equity | $ 23,892,280 | $ 17,934,303 |

See accompanying notes.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Revenues | $ — | $ — | $ 25,000 | $ 25,000 |
| Operating expenses: | | | | |
| Research and development | 1,831,347 | 2,587,902 | 5,777,173 | 7,101,923 |
| General and administrative | 709,028 | 785,714 | 2,238,711 | 2,512,002 |
| Total operating expenses | 2,540,375 | 3,373,616 | 8,015,884 | 9,613,925 |
| Operating loss | (2,540,375) | (3,373,616) | (7,990,884) | (9,588,925) |
| Interest income (expense): | | | | |
| Interest income | 47,884 | 115,021 | 162,956 | 380,935 |
| Interest expense | (8,312) | (11,142) | (33,364) | (19,021) |
| Total interest income, net | 39,572 | 103,879 | 129,592 | 361,914 |
| Loss before taxes | (2,500,803) | (3,269,737) | (7,861,292) | (9,227,011) |
| Taxes | — | — | — | — |
| Net loss | $ (2,500,803) | $ (3,269,737) | $ (7,861,292) | $ (9,227,011) |
| Basic and diluted net loss per share | $ (0.15) | $ (0.24) | $ (0.53) | $ (0.68) |
| Shares used in computation of basic and diluted net loss per share | 16,666,661 | 13,662,343 | 14,701,467 | 13,525,243 |

See accompanying notes.

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2003** | **2002** |
| **Operating activities**: | | |
| Net loss | $ (7,861,292) | $ (9,227,011) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation | 271,467 | 261,790 |
| Amortization of net premium on marketable securities | 13,305 | 206,530 |
| Changes in operating assets and liabilities: | | |
| Other current assets | 113,755 | 48,704 |
| Accounts payable and accrued expenses | 635,334 | 1,185,109 |
| Net cash used in operating activities | (6,827,431) | (7,524,878) |
| **Investing activities:** | | |
| Purchases of capital equipment and leasehold improvements | (528,149) | (1,268,768) |
| Purchases of marketable securities | (14,978,337) | (25,517,473) |
| Proceeds from sales of marketable securities | 1,386,530 | 5,228,717 |
| Proceeds from maturities of marketable securities | 14,980,000 | 15,922,000 |
| Net cash provided by (used in) investing activities | 860,044 | (5,635,524) |
| **Financing activities:** | | |
| Proceeds from lease obligations | — | 491,355 |
| Payments on lease obligations | (101,962) | (49,368) |
| Proceeds from issuance of common stock | 13,308,213 | 12,687,965 |
| Net cash provided by financing activities | 13,206,251 | 13,129,952 |
| Change in cash and cash equivalents for the period | 7,238,864 | (30,450) |
| Cash and cash equivalents at beginning of period | 378,007 | 455,073 |
| Cash and cash equivalents at end of period | 7,616,871 | 424,623 |
| Marketable securities at end of period | 14,532,183 | 18,821,061 |
| Total cash, cash equivalents and marketable securities | $ 22,149,054 | $ 19,245,684 |
| Supplemental cash flow information: | | |
| Interest paid | $ 33,364 | $ 19,021 |
| 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 accompanying Balance Sheet at December 31, 2002 has been derived from audited financial statements included in the Company's Annual Report on Form 10-K for the year then ended.

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 Annual Report on 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Net income (loss) | $(2,500,803) | $(3,269,737) | $(7,861,292) | $(9,227,011) |
| Unrealized gain (loss) on marketable securities | (3,404) | 15,502 | (22,316) | (8,006) |
| Comprehensive income (loss) | $(2,504,207) | $(3,254,235) | $(7,883,608) | $(9,235,017) |

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

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

| | September 30, 2003 | December 31, 2002 |
|---|---|---|
| Cash and cash equivalents | $ 7,616,871 | $ 378,007 |
| Marketable securities | 14,532,183 | 15,955,997 |
| Total | $22,149,054 | $16,334,004 |

**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 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 September 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 September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2003 | 2002 | 2003 | 2002 |
| Net loss, as reported | $(2,500,803) | $(3,269,737) | $(7,861,292) | $ (9,227,011) |
| Add: Stock-based employee compensation expense included in reported net loss | — | — | — | — |
| Deduct: Stock-based employee compensation expense determined under the fair value based method | (171,702) | (458,051) | (518,228) | (1,260,487) |
| Pro forma net loss | $(2,672,505) | $(3,727,788) | $(8,379,520) | $(10,487,498) |
| Earnings per share: | | | | |
| Basic and diluted-as reported | $ (0.15) | $ (0.24) | $ (0.53) | $ (0.68) |
| Basic and diluted-pro forma | $ (0.16) | $ (0.27) | $ (0.57) | $ (0.78) |

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 1.128 and 1.154 as of September 30, 2003 and 2002, respectively, and (6) a risk-free interest rate of 3.07% and 3.82% as of September 30, 2003 and 2002, respectively.

**5. Common Stock**

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 judgments, 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.

**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 developing proprietary drugs utilizing its novel TOCOSOL™ drug delivery technology. Our goal is 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 utilizing 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) provide additional funding towards 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 value and 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 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) and tocopherol derivatives to solubilize and stabilize drugs for formulation enhancement. The TOCOSOL technology is particularly suited to injectable drugs that are poorly soluble in water. In addition, the TOCOSOL technology may also be used in future applications to formulate oral drugs with poor permeability or oral drugs that are subject to hydrolysis or oxidation.

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®, 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. We have completed patient enrollment in Phase 2a clinical trials for TOCOSOL Paclitaxel to evaluate safety and efficacy in multiple tumor types. We have demonstrated that TOCOSOL Paclitaxel can be administered to patients by a short 15-minute injection, compared to the typical one to 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$^2$ to 225 mg/m$^2$ every three weeks. The maximum tolerated dose (MTD) was estimated to be 200 mg/m$^2$ every three weeks, slightly higher than the approved dose of Taxol® at 175 mg/m$^2$ 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$^2$.

As of September 2003, patient enrollment in the Phase 2a clinical trials has been completed and all patients have been evaluated for initial efficacy results. We enrolled a total of 122 patients in the ovarian, non-small cell lung and bladder cancer studies. All 122 patients are evaluable, 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 according to the RECIST criteria. In summary, for all three Phase 2a studies to date, we have seen 34 objective responses and an additional 49 patients have been reported to have stable disease. Of the objective responses, 27 are partial responses and seven are complete responses. Under the RECIST criteria, 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 ³30% for at least 4 weeks. Stable disease is defined as no increase in any tumor size ³20%.

In the ovarian cancer study, all 52 enrolled patients have been evaluated for anti-tumor effect. Sixteen of the 52 evaluable patients (31%) were reported as objective responses, including 2 complete responses and 14 partial responses; 19 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 3 complete responses and 6 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.

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

| Cancer Type | No. Patients Evaluable | Stable Disease | Objective Responses (OR) | | | |
|---|---|---|---|---|---|---|
| | | | Partial Response | Complete Response | Total OR | % OR |
| **Ovarian** | **52** | **19** | **14** | **2** | **16** | **31%** |
| **NSCL** | **43** | **19** | **6** | **3** | **9** | **21%** |
| **Bladder** | **27** | **11** | **7** | **2** | **9** | **33%** |

In addition to the Phase 2a efficacy results, we are also monitoring patients for adverse events. The most significant adverse events expected with taxanes are peripheral neuropathy and neutropenia. To date, the incidence of Grade 3 or Grade 4 neutropenia across all studies is 33%, 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 9%, and no patients have experienced Grade 4 peripheral neuropathy. We believe these percentages compare favorably to the reported experience with Taxol. Dose reductions or delays due to toxicity of any sort are uncommon; approximately 75% 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 2,000 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. 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 recently initiated a randomized crossover clinical pharmacology study to compare TOCOSOL Paclitaxel and Taxol, with both drugs given at 175 $mg/m^2$ every three weeks (the approved dose of Taxol). If comparable pharmacokinetics of active paclitaxel can be shown between our product and Taxol, we would then conduct a single 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 for the treatment of inoperable or metastatic urothelial transitional cell cancers (mostly urinary bladder cancer), an indication for which there is currently no FDA-approved therapy. In October 2003, we announced that we were granted Fast Track designation by the FDA for the development of TOCOSOL Paclitaxel for this indication. We plan to initiate a Phase 2b study in bladder cancer using weekly dosing of TOCOSOL Paclitaxel by the end of 2003.

- *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 (SNDA's) 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 continuing the clinical development of the product, we are also seeking to secure a corporate partner for TOCOSOL Paclitaxel to provide additional funding towards the remaining clinical development costs and also to maximize the commercial success of the product subsequent to product approval. During the first half of 2003, the primary need for entering into a corporate partner agreement was to secure additional financial resources in order to initiate the new clinical studies for TOCOSOL Paclitaxel by the end of 2003 under our comprehensive regulatory strategy. However, we completed a private placement of common stock in July 2003 for $14.2 million, which significantly increased our existing cash resources ($22.1 million at September 30). We continue to have an objective of securing a corporate partner for TOCOSOL Paclitaxel with an objective of maximizing both the value of the product to date and the commercial value subsequent to product approval.

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Research Product Pipeline

We continue to invest in the research and development of new products, including those that could extend the application of our TOCOSOL drug delivery technology. Our second product utilizing the TOCOSOL drug delivery technology is a novel injectable formulation of 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. In addition to camptothecin, we are evaluating a number of other earlier-stage therapeutic drug formulations utilizing our TOCOSOL drug delivery technology. 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. Advancing one or more of these potential products into human clinical trials is dependent on several factors including technological feasibility, commercial opportunity, and securing additional financial resources.

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 26 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. We have also received Notice of Allowance for three of the previously filed patent applications, which means that patent issuance for these applications is expected within the next three to six months. 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 September 30, 2003, our accumulated deficit was approximately $48.2 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 third quarter of 2003 or 2002. For the nine months ended September 30, 2003 and September 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 third quarter of 2003 were $2.5 million compared with $3.4 million in the third quarter of 2002. The decline in operating expenses from the prior year was primarily due to lower research and development expenses ($1.8 million in the third quarter of 2003 compared to $2.6 million in the third quarter of 2002) as well as lower general and administrative expenses ($709,000 in the third quarter of 2003 compared to $786,000 in the third quarter of 2002). For the first nine months of 2003, total operating expenses were $8.0 million compared to $9.6 million for the prior year period. The decrease primarily reflected the completion of the Phase 2a 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 $40,000 and $130,000 for the three and nine months ended September 30, 2003 compared with $104,000 and $362,000 for the same periods in 2002. The decline in net interest income for both periods was primarily due to generally lower levels of invested cash in the current year as well as 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 September 30, 2003, we had cash, cash equivalents and marketable securities of $22.1 million compared to $16.3 million at December 31, 2002. The increase was primarily due to the $13.1 million in net proceeds from the private placement in July 2003, offset in part by the $7.9 million net loss for the first nine months of 2003.

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 early 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 timing and costs of preclinical development, 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.

We also have contractual commitments in the form of operating leases, capital leases and leasehold financing arrangements as of September 30, 2003 as listed in the following table:

| | Total | 2003 | 2004 | 2005 | 2006 | 2007 |
|---|---|---|---|---|---|---|
| Facility Lease | $2,589,000 | $121,000 | $678,000 | $679,000 | $694,000 | $417,000 |
| Capital Leases | 213,000 | 30,000 | 129,000 | 54,000 | — | — |
| Leasehold Financing | 95,000 | 4,000 | 22,000 | 25,000 | 27,000 | 17,000 |
| Total | $2,897,000 | $155,000 | $829,000 | $758,000 | $721,000 | $434,000 |

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 judgments including those related to revenue recognition and research and development costs. Management bases its estimates and judgments 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 September 30, 2003, our accumulated deficit totaled $48.2 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 preclinical development, 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

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. During the second quarter of 2003 we completed enrollment in the current Phase 2a 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. 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 affect 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.

*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 early 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 timing and costs of preclinical development, 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.

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.

*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 September 30, 2003, we had stockholders' equity of $21.1 million. 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.

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 26 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. We have also received Notice of Allowance for three of the previously filed patent applications, which means that patent issuance for these applications is expected within the next three to six months. 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 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 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 September 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**

Information regarding the sale of equity securities by us during the period covered by this report that were not registered under the Securities Act of 1933, as amended, is set forth in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2003.

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

**(a) Exhibits**

| | |
|---|---|
| 31.1 | Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a). |
| 31.2 | Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a). |
| 32.1 | Certification of President and Chief Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b). |
| 32.2 | Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b). |

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

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

1. The Registrant filed a report on Form 8-K on July 10, 2003 in connection with the Company's second quarter conference call.
2. The Registrant filed a report on Form 8-K on August 8, 2003 in connection with the Company's private placement financing in July 2003.

**Items 1, 3, 4 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: November 14, 2003

By: /s/ Richard J. Klein

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

EXHIBIT 31.1

CERTIFICATION PURSUANT TO RULE 13A-14(a) OR RULE 15D-14(a) 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: November 14, 2003

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

EXHIBIT 31.2

CERTIFICATION PURSUANT TO RULE 13A-14(a) OR RULE 15D-14(a) 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: November 14, 2003

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

EXHIBIT 32.1

CERTIFICATION PURSUANT TO RULE 13A-14(b) OR RULE 15D-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934 AND U.S.C. SECTION 1350

I, Michael A. Martino, President and Chief Executive Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 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: November 14, 2003

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

EXHIBIT 32.2

CERTIFICATION PURSUANT TO RULE 13A-14(b) OR RULE 15D-14(b) OF THE SECURITIES EXCHANGE ACT OF 1934 AND U.S.C. SECTION 1350

I, Richard J. Klein, Chief Financial Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 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: November 14, 2003

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