U.S. SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2004

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 [X] No [ ]

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

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 2, 2004**
Common Stock, $.001 par value	21,299,319

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Part I. Financial Information

Item 1. Financial Statements

Sonus Pharmaceuticals, Inc.

Balance Sheets

	June 30, 2004	December 31, 2003
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 28,727,672	$ 19,663,595
Other current assets	249,907	198,584
Total current assets	28,977,579	19,862,179
Property and equipment, net	1,527,634	1,606,061
Total assets	$ 30,505,213	$ 21,468,240
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,370,805	$ 1,886,571
Current portion of lease obligations	143,219	151,369
Total current liabilities	2,514,024	2,037,940
Lease obligations, less current portion	54,887	120,617
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; $.001 par value; 5,000,000 authorized; no shares issued or outstanding	—	—
Common stock; $.001 par value; 75,000,000 shares authorized; 21,294,319 and 17,957,452 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	86,087,918	70,085,299
Accumulated deficit	(58,119,556)	(50,779,764)
Accumulated other comprehensive (loss) income	(32,060)	4,148
Total stockholders' equity	27,936,302	19,309,683
Total liabilities and stockholders' equity	$ 30,505,213	$ 21,468,240

See accompanying notes.

Sonus Pharmaceuticals, Inc.

Statements of Operations
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Revenues	$ —	$ —	$ —	$ 25,000
Operating expenses:				
Research and development	2,660,226	2,314,195	5,228,255	3,945,828
General and administrative	1,156,654	802,232	2,202,804	1,529,683
Total operating expenses	3,816,880	3,116,427	7,431,059	5,475,511
Operating loss	(3,816,880)	(3,116,427)	(7,431,059)	(5,450,511)
Interest income (expense):				
Interest income	62,815	42,337	107,176	115,072
Interest expense	(7,347)	(12,055)	(15,909)	(25,052)
Total interest income, net	55,468	30,282	91,267	90,020
Loss before taxes	(3,761,412)	(3,086,145)	(7,339,792)	(5,360,491)
Taxes	—	—	—	—
Net loss	$ (3,761,412)	$ (3,086,145)	$ (7,339,792)	$ (5,360,491)
Basic and diluted net loss per share	$ (0.19)	$ (0.22)	$ (0.39)	$ (0.39)
Shares used in computation of basic and diluted net loss per share	19,970,164	13,740,747	19,008,088	13,718,870

See accompanying notes.

Sonus Pharmaceuticals, Inc.

Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2004	**2003**
Operating activities:		
Net loss	$ (7,339,792)	$ (5,360,491)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	258,343	181,697
Amortization of net premium on marketable securities	(42,141)	14,756
Changes in operating assets and liabilities:		
Other current assets	(51,323)	67,786
Accounts payable and accrued expenses	484,234	430,183
Net cash used in operating activities	(6,690,679)	(4,666,069)
Investing activities:		
Purchases of capital equipment and leasehold improvements	(179,916)	(358,330)
Purchases of marketable securities	(19,458,036)	(4,910,711)
Proceeds from sales of marketable securities	2,070,834	1,386,531
Proceeds from maturities of marketable securities	10,000,000	13,550,000
Net cash (used in) provided by investing activities	(7,567,118)	9,667,490
Financing activities:		
Payments on lease obligations	(73,880)	(67,162)
Proceeds from issuance of common stock under equity financings, net	14,441,028	—
Proceeds from exercise of common stock warrants	1,409,884	—
Proceeds from issuance of common stock under employee benefit plans	151,707	61,941
Net cash provided by (used in) investing activities	15,928,739	(5,221)
Increase in cash and cash equivalents for the period	1,670,942	4,996,200
Cash and cash equivalents at beginning of period	1,709,017	378,007
Cash and cash equivalents at end of period	3,379,959	5,374,207
Marketable securities at end of period	25,347,713	5,896,509
Total cash, cash equivalents and marketable securities	$ 28,727,672	$11,270,716
Supplemental cash flow information:		
Interest paid	$ 15,909	$ 25,052

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, 2003 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, 2003 and filed with the Securities and Exchange Commission on March 12, 2004.

2. Comprehensive Income (Loss)

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Net loss	$(3,761,412)	$(3,086,145)	$(7,339,792)	$(5,360,491)
Unrealized loss on marketable securities	(39,616)	(8,099)	(36,208)	(18,912)
Comprehensive loss	$(3,801,028)	$(3,094,244)	$(7,376,000)	$(5,379,403)

3. Cash, Cash Equivalents and Marketable Securities

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

	June 30, 2004	December 31, 2003
Cash and cash equivalents	$ 3,379,959	$ 1,709,017
Marketable securities	25,347,713	17,954,578
	$28,727,672	$19,663,595

4. Stockholders' Equity

In May 2004, the Company sold 2.9 million shares of common stock in a private placement transaction for gross proceeds of $15.2 million (approximately $14.4 million net of transaction costs). The common stock was sold at a price of $5.25 per share.

During the second quarter of 2004, the Company recorded $494,000 in proceeds from the issuance of 121,000 shares of common stock from the exercise of common stock warrants and an additional $134,000 in proceeds from the issuance of 87,000 shares of common stock under employee benefit programs. For the six month period ended June 30, 2004, the Company recorded $1.4 million in proceeds from the issuance of 345,000 shares of common stock from the exercise of common stock warrants and an additional $152,000 in proceeds from the issuance of 92,000 shares of common stock under employee benefit programs.

In May 2004, at the annual meeting of shareholders of the Company, the shareholders approved an amendment of the Company's articles of incorporation to increase the authorized shares of common stock from 30.0 million to 75.0 million shares. The certificate of amendment to the articles of incorporation was filed with the State of Delaware in May 2004.

5. 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 June 30, 2004 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,	
	2004	2003	2004	2003
Net loss, as reported	$(3,761,412)	$(3,086,145)	$(7,339,792)	$(5,360,491)
Add: Stock-based employee compensation expense included in reported net loss	—	—	—	—
Deduct: Stock-based employee compensation expense determined under the fair value based method	(465,598)	(139,732)	(855,964)	(346,526)
Pro forma net loss	$(4,227,010)	$(3,225,877)	$(8,195,756)	$(5,707,017)
Earnings per share:				
Basic and diluted-as reported	$ (0.19)	$ (0.22)	$ (0.39)	$ (0.39)
Basic and diluted-pro forma	$ (0.21)	$ (0.23)	$ (0.43)	$ (0.42)

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 1.097 and 1.135 as of June 30, 2004 and 2003, respectively, and (6) a risk-free interest rate of 3.93% and 2.36% as of June 30, 2004 and 2003, respectively.

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, filing strategies and related 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. Please read "Certain Factors That May Affect Our Business and Future Results" below. You should consider the risks below carefully in addition to other information contained in this report 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;
- future prospects heavily dependent on clinical trial results of TOCOSOL® Paclitaxel;
- history of operating losses and uncertainty of future financial results;
- uncertainty of governmental regulatory requirements and lengthy approval process;
- dependence on third parties for funding, clinical development, manufacturing and distribution;
- future capital requirements and uncertainty of additional funding;
- uncertainty of U.S. or international legislative or administrative actions;
- 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;
- continued listing on the Nasdaq National Market; and
- volatility in the value of our common stock.

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 focused on the development of novel drugs for the oncology market that may offer improved administration, tolerability, safety and effectiveness. Our business strategy is as follows:

- develop proprietary formulations of therapeutic drugs utilizing our TOCOSOL drug delivery technology;
- collaborate with other pharmaceutical or biotech companies to apply the TOCOSOL technology to the formulation of their proprietary products or compounds; and
- identify and acquire additional therapies for the treatment or support of cancer patients in order to expand our product pipeline and corporate capabilities.

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 improved dosing convenience, decreased incidences of side effects and equivalent or better efficacy. The TOCOSOL technology uses vitamin E oil (tocopherol) and tocopherol derivatives to solubilize and stabilize drugs for formulation enhancement. While the TOCOSOL technology is particularly suited to injectable drugs that are poorly soluble in water, research is ongoing into the application of new versions of this technology that could prove applicable to oral or other routes of delivery as well.

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, a member of the taxane family of cancer drugs, 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 believe that clinical trials to date have demonstrated that TOCOSOL Paclitaxel compares favorably with approved taxane products and other new paclitaxel formulations under development (safety and efficacy remain to be proven), offers the convenience of a ready-to-use formulation that does not require time consuming preparation prior to administration, 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 taxane products, does not require any special I.V. tubing, filters or other apparatus and does not require dilution which results in administration of small volumes of 25 to 35 milliliters compared to several hundred milliliters for Taxol®.

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 three 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 (under the RECIST criteria, partial response is defined as reduction in the sums of the longest tumor dimensions of ³30% for at least four weeks). 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 in the Phase 1 study.

We initiated Phase 2a studies for TOCOSOL Paclitaxel in March 2002 to evaluate the safety and efficacy of 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 was 120 mg/m^2.

Patient enrollment in the Phase 2a clinical trials was completed in the second quarter of 2003 and all patients have been evaluated for initial efficacy results. A total of 120 patients in the ovarian, non-small cell lung and bladder cancer studies are evaluable, which means that the patients have received at least eight weekly cycles of TOCOSOL Paclitaxel and have had at least one CT scan to confirm anti-tumor responses according to the RECIST criteria.

In the ovarian cancer study, 51 enrolled patients have been evaluated for anti-tumor effect. Twenty of the 51 evaluable patients (39%) were reported as having objective responses, including three complete responses (under the RECIST criteria, complete response is defined as no evidence of remaining tumor, confirmed on two CT scans at least four weeks apart) and 17 partial responses; 16 additional patients were reported to have stable disease.

In the non-small cell lung cancer study, 42 enrolled patients have had anti-tumor effect evaluated. Nine of the 42 evaluable patients (21%) were reported as having objective responses, including three complete responses and six partial responses; 18 additional patients were reported to have stable disease.

In the bladder cancer study, 27 patients enrolled have had anti-tumor effect evaluated. Nine of the 27 evaluable patients (33%) were reported as having objective responses, including two complete responses and seven partial responses; 11 additional patients were reported to have stable disease.

The current Phase 2a clinical efficacy results are summarized in the table below:

Cancer Type	No. Patients Evaluable	Stable Disease	Objective Responses (OR)			
			Partial Response	Complete Response	Total OR	% OR
Ovarian	**51**	**16**	**17**	**3**	**20**	**39%**
NSCL	**42**	**18**	**6**	**3**	**9**	**21%**
Bladder	**27**	**11**	**7**	**2**	**9**	**33%**

In addition to efficacy results, we are also monitoring patients for adverse events in the Phase 2a studies. 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 36%, 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 10%, and no patients have experienced Grade 4 peripheral neuropathy. We believe these percentages compare favorably to the reported experience with Taxol® administered at the approved dose of 175 mg/m^2 every three weeks. Dose reductions or treatment delays due to toxicity of any sort are uncommon with TOCOSOL Paclitaxel. At the highest dose tested, 120 mg/m^2 weekly, 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 or 4 severity. Again, these frequencies compare favorably with reported rates of infusion reactions upon administration of available paclitaxel products. Investigators have reported that 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 U.S. Food and Drug Administration (FDA), we have outlined a regulatory strategy for TOCOSOL Paclitaxel that includes three development paths. Our goal with the regulatory strategy is to gain the fastest possible market entry with a competitive label while in parallel pursuing opportunities to expand the label indications to further differentiate the product. Our strategy for product approval includes parallel development under three separate paths explained below.

- *505(b)(2).* We will seek initial approval of TOCOSOL Paclitaxel with a 505(b)(2) New Drug Application (NDA) submission, which relies on the FDA's previous findings of safety and effectiveness of an approved product (Taxol®), 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. In the fourth quarter of 2003, we 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). In this trial, which is the first clinical step of our 505(b)(2) regulatory plan, each patient received a single dose of TOCOSOL Paclitaxel and a single dose of Taxol, with the doses given in random order at least three weeks apart. After each dose, multiple blood specimens were taken at specified times for five days to measure the amount of paclitaxel in circulation over time. We also looked at the effects of each drug on blood cell counts and other laboratory tests. We recently completed enrollment in this study with 31 evaluable patients, and based on our preliminary assessment of the data, we believe that TOCOSOL® Paclitaxel is delivering at least as much active drug as Taxol®. We are currently evaluating the data and preparing our proposal for Phase 3 clinical testing of TOCOSOL Paclitaxel. We expect to

submit the data and Phase 3 plans to the FDA before the end of the third quarter of 2004. When we initiated our 505(b)(2) strategy, our objective was to submit a NDA in late 2005 or early 2006 seeking approval of TOCOSOL Paclitaxel based on a single small confirmatory efficacy trial. We continue to believe that the clinical pharmacology data will support our 505(b)(2) strategy for approval; however, the actual design and timing of our Phase 3 program and resulting NDA submission will be determined through our discussions with the FDA after their review of the data from our clinical pharmacology study and proposed plans for Phase 3 testing.

- *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 cancers), 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 initiated a Phase 2b study in bladder cancer using weekly dosing of TOCOSOL Paclitaxel in the fourth quarter of 2003.

- *Further differentiation.* We will conduct trials in other 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 TOCOSOL 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, and provide supportive data for both a 505(b)(2) NDA or for a standard NDA submission in the event that the 505(b)(2) strategy is unsuccessful. We plan to initiate a Phase 2b study in breast cancer during 2004.

In addition to continuing the clinical development of the product, we are also seeking to secure one or more corporate partners 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.

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. We are currently evaluating a number of early stage therapeutic drug formulations utilizing the TOCOSOL technology, including potential product candidates based on the camptothecin molecule. The camptothecin molecule family 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 Hycamtin®, is indicated for treatment of ovarian and non-small cell lung cancers. Our research and development efforts on these product candidates are preliminary and we cannot give any assurance that any of these compounds will be successful or that they will progress to clinical trials. 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.

In addition to our internal research and development efforts, we may consider the acquisition of complementary products and technologies to expand our product pipeline.

Proprietary Technology

We consider the protection of our technology to be important to our business. In addition to seeking U.S. patent protection for our inventions, we are also seeking patent protection in other countries in order to broadly protect our proprietary rights. 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 and defend patents and protect trade secrets. As of June 30, 2004, six United States patents have issued pertaining to our TOCOSOL® drug delivery platform and other technologies. Additional patent applications are pending in the United States and counterpart filings have been made in Europe, Canada and key countries in Asia and Latin America.

Results of Operations

As of June 30, 2004, our accumulated deficit was approximately $58.1 million. We may incur substantial 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 and the purchase of technology. Substantially all of our working capital in recent years has resulted from equity financings. Historically, substantially all of our revenue 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, 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.

For the three months ended June 30, 2004 and 2003, the Company reported no revenue. For the six months ended June 30, 2004 and 2003, the Company reported revenue of $0 and $25,000, respectively. Revenues for the remainder of 2004 will be dependent on our ability to enter into new collaborative agreements or licensing arrangements with third parties.

For the three months ended June 30, 2004, total operating expenses were $3.8 million compared with $3.1 million for the prior year period. The increase in operating expenses from the prior year was primarily due to higher research and development expenses ($2.7 million for the three months ended June 30, 2004 compared to $2.3 million for the prior year period) as well as higher general and administrative expenses ($1.2 million for the three months ended June 30, 2004 compared to $802,000 for the prior year period). For the first six months of 2004, total operating expenses were $7.4 million compared to $5.5 million for the prior year period. The increase in operating expenses over the prior year for the three and six month periods ended June 30, 2004 was primarily related to higher spending on the clinical trial programs related to our lead cancer product, TOCOSOL Paclitaxel, as it advances through development as well as increased personnel and business development costs.

Net interest income was $55,000 and $91,000 for the three and six months ended June 30, 2004 compared with $30,000 and $90,000 for the same periods in 2003. The increase in net interest income for the second quarter was primarily due to higher levels of invested cash, cash equivalents and marketable securities in the current year.

Liquidity and Capital Resources

We have historically financed operations with proceeds from equity financings and payments under contractual agreements with third parties. At June 30, 2004, we had cash, cash equivalents and marketable securities of $28.7 million compared to $19.7 million at December 31, 2003. The increase was primarily due to the $14.4 million in net proceeds from the private placement of 2.9 million shares of common stock in May 2004, $1.4 million in proceeds from the issuance of 345,000 shares of common stock from the exercise of common stock warrants and $152,000 in proceeds from the issuance of 92,000 shares of common stock under employee benefit programs. These increases were offset in part by the $7.3 million net loss for the first six months of 2004.

We expect that our cash requirements will increase in future periods due to development costs associated with our TOCOSOL drug delivery products. Based on our current operating plan, including planned clinical trials and other product development costs, we estimate that existing cash and marketable securities will be sufficient to meet our cash requirements for at least the next 12 months. We will need additional capital to complete the development of TOCOSOL Paclitaxel and other product candidates. Our future capital requirements depend on many factors including:

- timing and costs of preclinical development, clinical trials and regulatory approvals;
- entering into new collaborative or product license agreements;
- timing and costs of technology transfer associated with manufacturing and supply agreements;
- our ability to obtain and 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.

We have contractual obligations in the form of capital leases, operating leases and leasehold financing arrangements. We have remaining contractual obligations through 2007 under our operating leases of $2.2 million and $198,000 under our capital lease and leasehold financing agreements. The following table summarizes our contractual obligations as of June 30, 2004:

	Obligations due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Capital lease/lease financing obligations	$ 198,106	$143,219	$ 54,887	$ —	$ —
Operating lease obligations	2,158,706	690,606	1,405,512	62,588	—
Total:	$2,356,812	$833,825	$1,460,399	$62,588	$ —

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. Most of our attention and resources are directed to the development of TOCOSOL, a drug delivery technology that provides 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 based products under development or any future products will be safe or efficacious. If the TOCOSOL based products under development are ultimately ineffective in treating cancer, do not receive the necessary regulatory approvals or do not obtain commercial acceptance, we will be materially adversely affected.

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, 2004, our accumulated deficit totaled $58.1 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 is not likely to 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:

- timing and costs of preclinical development, clinical trials and regulatory approvals;
- entering into new collaborative or product license agreements;
- timing and costs of technology transfer associated with manufacturing and supply agreements;
- our ability to obtain and 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 submit an application to 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 to middle stages of development and are subject to regulatory approval. The results of preclinical 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.

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.

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. 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 for at least the next 12 months. We will need additional capital to complete the development of TOCOSOL Paclitaxel and other product candidates. Our future capital requirements depend on many factors including:

- timing and costs of preclinical development, clinical trials and regulatory approvals;
- entering into new collaborative or product license agreements;

- timing and costs of technology transfer associated with manufacturing and supply agreements;
- our ability to obtain and 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.

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 payor 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 taxane 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 and may drop significantly before we achieve regulatory approval.

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. We have entered into supply agreements for the supply of GMP grade paclitaxel, which is the active pharmaceutical 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. As of June 30, 2004, six United States patents have issued pertaining to our TOCOSOL® drug delivery platform and other technologies. Additional patent applications are pending in the United States and counterpart filings have been made in Europe, Canada 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 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 payors 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 payors 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. 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.

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, 2004, we had stockholders’ equity of approximately $27.9 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 National Association of Securities Dealer’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.

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 or pharmaceutical 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, 2004, the decline in the fair value of our 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, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon the evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures are effective in timely alerting management to material information required to be included in our periodic SEC filings. Our Chief Financial Officer resigned in April 2004 and until we find a replacement, our Chief Executive Officer is performing the functions of our principle executive and principle financial officer.

Part II. Other Information

Item 2. Changes in Securities and Use of Proceeds

In May 2004, Sonus sold 2,900,000 shares of its common stock for a purchase price of $5.25 per share. The aggregate purchase price of the common stock was approximately $15.2 million, resulting in net proceeds to Sonus of approximately $14.4 million. Sonus and the investors concurrently entered into a Registration Rights Agreement under which Sonus filed a registration statement under the Securities Act of 1933, as amended, to register for resale all of the shares of common stock in the offering. The shares of common stock were sold to new 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 common stock 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 common stock issued by Sonus. The offering was conducted without any general solicitation or advertising.

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

Our Annual Meeting of Stockholders was held on May 5, 2004. At the Annual Meeting, there were three matters submitted to a vote of security holders. Proxies were solicited pursuant to Regulation 14A of the Securities Exchange Act of 1934. There was no solicitation in opposition to management's nominees as listed in the proxy statement.

Each director nominated and all other proposals submitted to a vote passed and the voting outcome of each proposal was as follows:

1. Election of the following four (4) directors to serve until the next annual meeting of stockholders or until their successors are elected and have qualified to serve as directors:

Nominee	For	Abstain
Michael A. Martino	13,234,004	351,558
George W. Dunbar, Jr.	12,955,357	630,205
Robert E. Ivy	13,235,104	350,458
Dwight Winstead	12,952,357	633,205

2. Approve an amendment to the Company's Certificate of Incorporation to increase the number of authorized shares of Common Stock of the Company to 75,000,000 shares.

For: 12,486,707 Against: 1,063,089 Abstain: 35,766

3. Ratification of Ernst & Young LLP as independent auditors of the Company for the fiscal year ending December 31, 2004:

For: 13,501,448 Against: 51,748 Abstain: 32,366

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

3.5 Amended and Restated Certificate of Incorporation of the Company.

31.1 Certification of President and Chief Executive 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).

(b) Reports on Form 8-K

The Company filed the following reports on Form 8-K during the quarter ended June 30, 2004:

1. The Registrant filed a report on Form 8-K on April 21, 2004 in connection with the release of the Company's first quarter financial results and associated quarterly conference call.

2. The Registrant filed a report on Form 8-K May 13, 2004 in connection with the Company's private placement financing in May 2004.

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 16, 2004

By: /s/ Michael A. Martino

Michael A. Martino
President and Chief Executive Officer
(Principal Executive and Principle Financial Officer)

Exhibit 3.5

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION

OF

SONUS PHARMACEUTICALS, INC.

(AS AMENDED THROUGH MAY 5, 2004)

ARTICLE I - NAME

The name of this Corporation is SONUS Pharmaceuticals, Inc.

ARTICLE II -- REGISTERED OFFICE AND AGENT

The address of registered office of the Corporation in the State of Delaware is 32 Loockerman Square, Suite L-100, Dover, County of Kent, Delaware 19901. The name of its registered agent at such address is The Prentice-Hall Corporation System, Inc., County of Kent.

ARTICLE III -- PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware, as amended from time to time.

ARTICLE IV -- AUTHORIZED CAPITAL

This Corporation is authorized to issue two classes of stock to be designated respectively, "Common Stock" and "Preferred Stock." The total number of shares of all classes of stock which the Corporation shall have authority to issue is 80,000,000, of which (i) 75,000,000 shares shall be designated Common Stock and shall have a par value of $.001 per share; and (ii) 5,000,000 shares shall be designated Preferred Stock and shall have a par value of $.001 per share. The Board of Directors is authorized, subject to limitations prescribed by law, to provide for the issuance of the shares of Preferred Stock in one or more series, and by filing a certificate pursuant to the applicable law of the State of Delaware, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The authority of the Board with respect to each series shall include, but not be limited to, determination of the following:

(a) The number of shares constituting that series and the distinctive designation of that series;

(b) The dividend rate on the shares of that series, whether dividends shall be cumulative and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series;

(c) Whether that series shall have voting rights, in addition to the voting rights provided by law and, if so, the terms of such voting rights;

(d) Whether that series shall have conversion privileges and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the Board of Directors shall determine;

(e) Whether or not the shares of that series shall be redeemable and, if so, the terms and conditions of such redemption, including the date or dates upon or after which they shall be redeemable and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates;

(f) Whether that series shall have a sinking fund for the redemption or purchase of shares of that series and, if so, the terms and amount of such sinking fund; and

(g) The rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Corporation, and the relative rights of priority, if any, of payment of shares of that series.

ARTICLE V -- BOARD OF DIRECTORS AND MEETINGS OF STOCKHOLDERS

Section 1. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors and elections of directors need not be by written ballot unless otherwise provided in the Bylaws. The number of directors of the Corporation shall be fixed from time to time by the Board of Directors either by a resolution or Bylaw adopted by the affirmative vote of a

majority of the entire Board of Directors.

Section 2. Meetings of the stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept (subject to any provision contained in the Delaware Statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or by the Bylaws of the Corporation.

ARTICLE VI -- LIMITATION OF DIRECTORS' LIABILITY

A director of this Corporation shall not be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except to the extent that exculpation from liability is not permitted under the General Corporation Law of the State of Delaware as in effect at the time such liability is determined. No amendment or repeal of this Article VI shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal.

ARTICLE VII -- INDEMNIFICATION OF OFFICERS AND DIRECTORS

This Corporation shall, to the maximum extent permitted from time to time under the law of the State of Delaware, indemnify and upon request shall advance expenses to any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action, suit, proceeding or claim, whether civil, criminal, administrative or investigative, by reason of the fact that such person is or was or has agreed to be a director or officer of this Corporation or while a director or officer is or was serving at the request of this Corporation as a director, officer, partner, trustee, employee or agent of any corporation, partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, against expenses (including attorney's fees and expenses), judgments, fines, penalties and amounts paid in settlement incurred in connection with the investigation, preparation to defend or defense of such action, suit, proceeding or claim; provided; however, that the foregoing shall not require this Corporation to indemnify or advance expenses to any person in connection with any action, suit, proceeding, claim or counterclaim initiated by or on behalf of such person. Such indemnification shall not be exclusive of other indemnification rights arising under any by-law, agreement, vote of directors or stockholders or otherwise and shall inure to the benefit of the heirs and legal representatives of such person. Any person seeking indemnification under this Article VII shall be deemed to have met the standard of conduct required for such indemnification unless the contrary shall be established. Any repeal or modification of the foregoing provisions of this Article VII shall not adversely affect any right or protection of a director or officer of this corporation with respect to any acts or omissions of such director or officer occurring prior to such repeal or modification.

ARTICLE VIII -- AMENDMENT OF BYLAWS

In furtherance and not in limitation of the power conferred upon the Board of Directors by law, the Board of Directors shall have the power to make, adopt, alter, amend and repeal from time to time Bylaws of this corporation, subject to the right of the stockholders entitled to vote with respect thereto to alter and repeal Bylaws made by the Board of Directors.

ARTICLE IX -- ACTION BY MEETINGS

Stockholders of the Corporation may not take action by written consent in lieu of a meeting. Any action contemplated by the stockholders must be taken at a duly called annual or special meeting.

ARTICLE X -- CUMULATIVE VOTING

At all elections of directors of the Corporation, each stockholder of the Corporation shall be entitled to as many votes as shall equal the number of votes which the stockholder would be entitled to cast for the election of directors with respect to the stockholder's shares of stock multiplied by the number of directors to be elected by the stockholders, and each stockholder may cast all of such votes for a single director or may distribute them among the number to be voted for, or for any two or more of them as the stockholder may see fit.

ARTICLE XI -- AMENDMENT OF CERTIFICATE OF INCORPORATION

The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

ARTICLE XIII -- PERPETUAL EXISTENCE

The Corporation is to have perpetual existence.

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; and

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 the registrant's board of directors (or persons performing the equivalent functions):

   (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 16, 2004

/s/ Michael A. Martino

Michael A. Martino
President and Chief Executive 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 June 30, 2004 (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 16, 2004

/s/ Michael A. Martino

Michael A. Martino
President and Chief Executive Officer