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
SEPTEMBER 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 November 2, 2004
Common Stock, $.001 par value	21,347,977

Sonus Pharmaceuticals, Inc.
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Part I. Financial Information

Item 1. Financial Statements

Sonus Pharmaceuticals, Inc.

Balance Sheets

	September 30, 2004	December 31, 2003
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 1,711,915	$ 1,709,017
Marketable securities	23,289,508	17,954,578
Other current assets	261,416	147,084
Total current assets	25,262,839	19,810,679
Property and equipment, net	1,523,400	1,606,061
Other assets	51,500	51,500
Total assets	$ 26,837,739	$ 21,468,240
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 2,253,055	$ 1,886,571
Current portion of lease obligations	111,215	151,369
Total current liabilities	2,364,270	2,037,940
Lease obligations, less current portion	48,609	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; 21,347,384 and 17,957,452 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	86,177,260	70,085,299
Accumulated deficit	(61,732,052)	(50,779,764)
Accumulated other comprehensive (loss) income	(20,348)	4,148
Total stockholders' equity	24,424,860	19,309,683
Total liabilities and stockholders' equity	$ 26,837,739	$ 21,468,240

See accompanying notes.

Sonus Pharmaceuticals, Inc.

Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenue	$ —	$ —	$ —	$ 25,000
Operating expenses:				
Research and development	2,401,403	1,831,347	7,629,657	5,777,173
General and administrative	1,290,853	709,028	3,493,657	2,238,711
Total operating expenses	3,692,256	2,540,375	11,123,314	8,015,884
Operating loss	(3,692,256)	(2,540,375)	(11,123,314)	(7,990,884)
Interest income (expense):				
Interest income	84,904	47,884	192,080	162,956
Interest expense	(5,145)	(8,312)	(21,054)	(33,364)
Total interest income, net	79,759	39,572	171,026	129,592
Loss before taxes	(3,612,497)	(2,500,803)	(10,952,288)	(7,861,292)
Taxes	—	—	—	—
Net loss	$ (3,612,497)	$ (2,500,803)	$(10,952,288)	$ (7,861,292)
Basic and diluted net loss per share	$ (0.17)	$ (0.15)	$ (0.55)	$ (0.53)
Shares used in computation of basic and diluted net loss per share	21,312,949	16,666,661	19,776,375	14,701,467

See accompanying notes.

Sonus Pharmaceuticals, Inc.

Statements of Cash Flows
(Unaudited)

	Nine Months Ended September 30,	
	2004	**2003**
Operating activities:		
Net loss	$ (10,952,288)	$ (7,861,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	401,788	271,467
Amortization of net (discount) premium on marketable securities	(43,990)	13,305
Changes in operating assets and liabilities:		
Other current assets	(114,332)	113,755
Accounts payable and accrued expenses	366,484	635,334
Net cash used in operating activities	(10,342,338)	(6,827,431)
Investing activities:		
Purchases of capital equipment and leasehold improvements	(319,127)	(528,149)
Purchases of marketable securities	(28,214,155)	(14,978,337)
Proceeds from sales of marketable securities	8,198,719	1,386,530
Proceeds from maturities of marketable securities	14,700,000	14,980,000
Net cash (used in) provided by investing activities	(5,634,563)	860,044
Financing activities:		
Payments on lease obligations	(112,162)	(101,962)
Proceeds from issuance of common stock under equity financings, net	14,440,667	13,148,709
Proceeds from exercise of common stock warrants	1,409,884	—
Proceeds from issuance of common stock under employee benefit plans	241,410	159,504
Net cash provided by investing activities	15,979,799	13,206,251
Increase in cash and cash equivalents for the period	2,898	7,238,864
Cash and cash equivalents at beginning of period	1,709,017	378,007
Cash and cash equivalents at end of period	$ 1,711,915	$ 7,616,871
Supplemental cash flow information:		
Interest paid	$ 21,054	$ 33,364

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. Certain prior year amounts have been reclassified to conform to the September 30, 2004 presentation.

2. Comprehensive Income (Loss)

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net loss	$(3,612,497)	$(2,500,803)	$(10,952,288)	$(7,861,292)
Unrealized gain (loss) on marketable securities	11,712	(3,404)	(24,496)	(22,316)
Comprehensive loss	$(3,600,785)	$(2,504,207)	$(10,976,784)	$(7,883,608)

3. 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 third quarter of 2004, the Company recorded $90,000 in proceeds from the issuance of 53,000 shares of common stock under employee benefit programs. For the nine month period ended September 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

$241,000 in proceeds from the issuance of 145,000 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.

4. Accounting for Stock Based Compensation

Under the provisions of SFAS No. 123, *"Accounting for Stock-Based Compensation,"* and amended by SFAS No. 148, *"Accounting for Stock-based Compensation — Transition and Disclosure"* 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, 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 September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net loss, as reported	$(3,612,497)	$(2,500,803)	$(10,952,288)	$(7,861,292)
Add: Stock-based employee compensation expense included in reported net loss	—	—	—	—
Deduct: Stock-based employee compensation expense determined under the fair value based method	(342,277)	(171,702)	(1,205,565)	(518,228)
Pro forma net loss	$(3,954,774)	$(2,672,505)	$(12,157,853)	$(8,379,520)
Earnings per share:				
Basic and diluted-as reported	$ (0.17)	$ (0.15)	$ (0.55)	$ (0.53)
Basic and diluted-pro forma	$ (0.19)	$ (0.16)	$ (0.61)	$ (0.57)

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 1.086 and 1.128 as of September 30, 2004 and 2003, respectively, and (6) a risk-free interest rate of 3.51% and 3.07% as of September 30, 2004 and 2003, respectively.

On March 31, 2004, the FASB issued an Exposure Draft,*"Share-Based Payment — An Amendment of FASB Statements No. 123 and 95"*(proposed SFAS 123R), which currently is expected to be effective for public companies in periods beginning after June 15, 2005. We would be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. The proposed FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. The proposed FAS 123R would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. As proposed, companies would be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans. The FASB expects to issue a final standard by December 31, 2004. We are currently evaluating option valuation methodologies and assumptions in light of the proposed FAS 123R related to employee stock options. Current estimates of option values using the Black-Scholes method (as shown above) may not be indicative of results from valuation methodologies ultimately adopted in the final rules.

5. Subsequent Event

On November 3, 2004, the Company entered into a Stock Purchase Agreement with the shareholders of Synt:em, S.A., a French société anonyme, whereby the Company agreed to purchase all of the outstanding capital stock of Synt:em for a price of approximately $30 million, consisting of an initial payment at closing of approximately $10 million, and two contingent payments of approximately $10 million each, conditional upon product candidates of Synt:em reaching Phase 1 clinical trials. The purchase price will be payable in shares of common stock of the Company based upon the average trading price for the 20 days ending 2 days before the closing, subject to upper and lower ownership collars based on fully diluted shares outstanding of the Company (using treasury stock method) on the closing date of 29% and 26%, respectively. Provided all milestones are achieved, Synt:em shareholders would be issued between approximately 7.6 million and 8.9 million shares of Sonus common stock depending on the closing price of Sonus stock. These shares would also be subject to lock-up periods that will expire 25% on the date that is nine months after the closing date and 25% at the end of each three-month period thereafter, such that all shares of Sonus common stock will be freely transferable on the eighteen month anniversary of the closing date. Synt:em is a drug discovery company using its proprietary drug design technologies to discovery and develop new drugs and drug transport conjugates in the areas of cancer, pain and central nervous system diseases. The transaction is subject to a number of conditions, including approval of the issuance of shares by the stockholders of the Company. The transaction is expected to close in the first quarter of 2005.

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 revenue 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 with future prospects heavily dependent on clinical trial results of TOCOSOL® Paclitaxel;
- costs and risks of integration of acquired companies;
- 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;
- dependence on key employees;
- 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;
- 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.

On November 3, 2004, the Company entered into a Stock Purchase Agreement with the shareholders of Synt:em, S.A., a French société anonyme, whereby the Company agreed to purchase all of the outstanding capital stock of Synt:em for a price of approximately $30 million, consisting of an initial payment at closing of approximately $10 million, and two contingent payments of approximately $10 million each, conditional upon product candidates of Synt:em reaching Phase 1 clinical trials. The purchase price will be payable in shares of common stock of the Company based upon the average trading price for the 20 days ending 2 days before the closing, subject to upper and lower ownership collars based on fully diluted shares outstanding of the Company (using treasury stock method) on the closing date of 29% and 26%, respectively. Provided all milestones are achieved, Synt:em shareholders would be issued between approximately 7.6 million and 8.9 million shares of Sonus common stock depending on the closing price of Sonus stock. These shares would also be subject to lock-up periods that will expire 25% on the date that is nine months after the closing date and 25% at the end of each three-month period thereafter, such that all shares of Sonus common stock will be freely transferable on the eighteen month anniversary of the closing date. Synt:em is a drug discovery company using its proprietary drug design technologies to discovery and develop new drugs and drug transport conjugates in the areas of cancer, pain and central nervous system diseases. The transaction is subject to a number of conditions, including approval of the issuance of shares by the stockholders of the Company. The transaction is expected to close in the first quarter of 2005.

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;
- identify and acquire additional therapies and technologies for the treatment or support of cancer patients in order to expand our product pipeline and corporate capabilities; and
- identify and acquire complimentary products and technologies in order to broaden our business and market opportunities.

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, making them easier to formulate and deliver into the body. While the TOCOSOL technology is particularly suited to injectable drugs that are poorly soluble in water, research continues into the application of new versions of this technology that could prove applicable to oral or other routes of delivery.

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 infusion, compared to the one- to three-hour infusion that is typically 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 sum of the longest tumor dimensions of ^{3}30% 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 in the Phase 2a trials 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 were evaluable 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 were evaluable for anti-tumor effect. 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 were evaluable for anti-tumor effect. 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 assessing anti-tumor efficacy, 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 9%, 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, 70% of planned doses were delivered on schedule at full dose for a median weekly dose across all patients of 105 mg/m^2. At the 100 mg/m^2 dose level, 84% of doses were delivered on schedule at full dose, for a median weekly dose of 96 mg/m^2. Paclitaxel-mediated infusion reactions, sometimes called “hypersensitivity reactions” and involving pain, flushing, shortness of breath or chest tightness, were infrequently observed following more than 2,000 administered doses. Only 15% of doses led to a reaction of any severity, and less than 1% of doses led to reactions that were of Grade 3 severity, i.e., requiring supportive treatment. There were no Grade 4 infusion reactions. 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 to have 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 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 the active ingredient in a drug product. 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 dosing regimen for Taxol). In this trial, which was 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 over 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. Earlier in 2004, we completed enrollment in this study with 36 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 prepared our initial assessment of the data and our proposal for Phase 3 clinical testing of TOCOSOL Paclitaxel, and have requested a face-to-face End of Phase 2 meeting with FDA to discuss the data and our proposed study. This meeting has been confirmed by the FDA. Our original guidance for the possible timing of submission of an NDA seeking approval of TOCOSOL Paclitaxel based on a single confirmatory efficacy trial was that it might occur as early as late 2005 or early 2006. We now believe that it will not be possible for the NDA to be submitted by the end of 2005. The revised estimated timing for submission will be determined once we have reached final agreement with the FDA on the full details and scope of the Phase 3 program. We hope to finalize agreement with the FDA on the Phase 3 clinical study design by year-end. After we reach agreement on the program we intend to pursue a Special Protocol Assessment for the Phase 3 trial of TOCOSOL Paclitaxel as a way of reducing uncertainty in the NDA review and approval process.

- *New indication for taxanes.* Under this component of our strategy, we will pursue approval for the use of TOCOSOL Paclitaxel as a treatment of inoperable or metastatic urothelial transitional cell cancers (mostly urinary bladder cancers), an indication for which there is an unmet medical need for effective, less toxic 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 in the U.S. using weekly dosing of TOCOSOL Paclitaxel in the fourth quarter of 2003. Enrollment in this trial has been challenging to-date due to the limited population of patients in this indication and the inconsistent standard of treatment for it. As previously indicated, we plan to open additional study sights in Europe in early 2005 to augment enrollment in this trial.

- *Further differentiation.* We intend to 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 could 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 505(b)(1) NDA submission in the event that the 505(b)(2) strategy is unsuccessful. We initiated a Phase 2b study in breast cancer during the third quarter of 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. 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 and commercial opportunity.

We believe that the pending acquisition of Synt:em offers the opportunity to expand our technology base and product candidate pipeline. In addition to our internal research and development efforts, we may consider other acquisitions 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 September 30, 2004, six United States patents have issued pertaining to our TOCOSOL® drug delivery platform and other technologies. A patent covering our TOCOSOL® drug delivery platform has also issued in Taiwan. 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 September 30, 2004, our accumulated deficit was approximately $61.7 million. We expect to continue to 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, future payments under corporate partnerships and licensing arrangements could be 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 September 30, 2004 and 2003, the Company reported no revenue. For the nine months ended September 30, 2004 and 2003, the Company reported revenue of $0 and $25,000, respectively. Revenue 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 September 30, 2004 and 2003, total operating expenses were $3.7 million and $2.5 million, respectively. The increase in operating expenses over the prior quarter was primarily due to higher research and development expenses in the current quarter ($2.4 million for the three months ended September 30, 2004 compared to $1.8 million for the prior year period) as well as higher general and administrative expenses in the current quarter ($1.3 million for the three months ended September 30, 2004 compared to $709,000 for the prior year period). For the nine months ended September 30, 2004 and 2003, total operating expenses were $11.1 million and $8.0 million, respectively. The increase in operating expenses over the prior year three and nine month periods 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, business development and Sarbanes-Oxley compliance costs in the current year periods.

For the three months ended September 30, 2004 and 2003, net interest income was $80,000 and $40,000, respectively. The increase in net interest income over the prior quarter was primarily due to higher levels of invested cash, cash equivalents and marketable securities in the current quarter. For the nine months ended September 30, 2004 and 2003, net interest income was $171,000 and $130,000, respectively. The increase in net interest income over the prior year period was primarily due to higher levels of invested cash, cash equivalents and marketable securities in the current period.

Liquidity and Capital Resources

We have historically financed operations with proceeds from equity financings and payments under contractual agreements with third parties. At September 30, 2004, we had cash, cash equivalents and marketable securities totaling $25.0 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 $241,000 in proceeds from

the issuance of 145,000 shares of common stock under employee benefit programs. These increases were offset in part by the $11.0 million net loss for the first nine months of 2004.

We expect that our cash requirements will continue to increase in future periods due to development costs associated with TOCOSOL Paclitaxel and other product candidates. There will also be additional cash requirements associated with our proposed acquisition, future operations and product development costs of Synt:em. Based on our current operating plan, including planned clinical trials, other product development costs, and operations of Synt:em, we estimate that existing cash, cash equivalents and marketable securities will be sufficient to meet our cash requirements for at least the next nine months. Our current operating plans include additional equity financing in 2005, which if successful, will provide us with a minimum of 12 months of cash. If we are unable to raise additional cash in 2005 through either an equity financing or business partnerships, we have the ability to scale back operations such that we would have 12 months of cash. In addition to funding planned in 2005, 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;
- drug discovery and research & development, including the operations of Synt:em;
- 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 in 2005 and beyond, we will have to substantially reduce our expenditures, scale back the development of our products and new product research and development, or out license 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 $2.0 million and $160,000 under our capital lease and leasehold financing agreements. The following table summarizes our contractual obligations as of September 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	$ 159,824	$111,215	$ 48,609	$ —	$ —
Operating lease obligations	1,984,567	688,031	1,295,336	1,200	—
Total:	$2,144,391	$799,246	$1,343,945	$1,200	$ —

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 revenue 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 may not be able to effectively or completely integrate the business and operations of Synt:em, which may cause the market price of our common stock to decline significantly.

We have entered into a Stock Purchase Agreement to acquire Synt:em. The closing of the transaction is subject to a number of conditions, including approval of our stockholders of the issuance of shares.

In connection with our acquisition of Synt:em, we face several significant challenges in integrating the business and operations of Synt:em with our own. There is no guarantee that we will be able to achieve the integration in an effective, complete, timely or cost-efficient manner. The acquisition of Synt:em will significantly increase our size, including with respect to number of employees and facilities. The integration of Synt:em with our operations involves substantial risks, including:

- our ability to finance the increased costs associated with development of the Synt:em operations and product development;
- our ability to integrate the products of Synt:em so they compliment our own;
- our ability to continue the production and development of the Synt:em products and underlying technology;
- our ability to retain key personnel who remain employed with Synt:em following the acquisition, and our ability to replace key personnel who do not remain employed with Synt:em following the acquisition;
- our ability to manufacture and pursue the development of the Synt:em products;
- our ability to successfully integrate the different corporate culture of Synt:em;
- our ability to integrate the international operations of Synt:em;
- our ability to expand our financial and management controls and reporting systems and

procedures including those related to the Sarbanes-Oxley Act of 2002, necessary for the integration and management of Synt:em;

- our ability to realize expected synergies resulting from the acquisition;
- diversion of management's time and attention;
- administrative integration and elimination of redundancies;
- assumption of unknown or contingent liabilities, or other unanticipated events or circumstances;

We cannot guarantee that the business and operations of Synt:em will achieve the anticipated strategies and operating results. We may in the future choose to not pursue the development of certain product candidates of Synt:em, which could require us to record losses relating to the termination of such programs. Any of the foregoing risks could materially harm our business, financial conditions and results of operations.

In addition, we may continue to consider acquisitions of other companies, technologies and complimentary products in the future to expand our product offerings and technology base to further our strategic goals. We expect that we would face the same and other similar risks as referenced above in connection with any such future acquisitions.

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, 2004, our accumulated deficit totaled $61.7 million. We anticipate that our operating losses will continue as we further invest in research and development for our products. We will incur additional costs and expenses in connection with the acquisition and operations of Synt:em. We will not generate any product revenue unless and until we receive regulatory approval, which is not likely to occur in the near future. Even if we generate significant product revenue, 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;
- drug discovery and research & development, including the operations of Synt:em;
- 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. There can be no assurance that the FDA will agree to our proposed 505(b)(2) regulatory strategy. 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, other product development costs, and operations of Synt:em, we estimate that existing cash, cash equivalents and marketable securities will be sufficient to meet our cash requirements for at least the next nine months. Our current operating plans include additional equity financing in 2005, which if successful, will provide us with a minimum of 12 months of cash. If we are unable to raise additional cash in 2005 through either an equity financing or business partnerships, we have the ability to scale back operations such that we would have 12 months of cash. 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 in 2005 and beyond, we will have to substantially reduce our expenditures, scale back the development of our products and new product research and development, or out license products that we otherwise would seek to commercialize ourselves, which could seriously harm our business, and explore other strategic alternatives.

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.

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 September 30, 2004, six United States patents have issued pertaining to our TOCOSOL® drug delivery platform and other technologies. A patent covering our TOCOSOL® drug delivery platform has also issued in Taiwan. 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.

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 September 30, 2004, we had stockholders' equity of approximately $24.4 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 September 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 and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon the evaluation, our Chief Executive Officer and Chief Financial 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. The Company appointed a new Chief Financial Officer on September 15, 2004.

Part II. Other Information

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 President and 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 President and 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, 2004:

1. The Registrant filed a report on Form 8-K on July 21, 2004 in connection with the release of the Company's second quarter financial results and associated quarterly conference call.
2. The Registrant filed a report on Form 8-K on September 20, 2004 in connection with the appointment of the new Chief Financial Officer.
3. The Registrant filed a report on Form 8-K on September 30, 2004 in connection with the submission of a meeting request with FDA.

Items 1, 2, 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 15, 2004

By: /s/ Michael A. Martino
Michael A. Martino
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Alan Fuhrman
Alan Fuhrman
Senior Vice President and 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; 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: November 15, 2004

/s/ Michael A. Martino

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, Alan Fuhrman, 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: November 15, 2004

/s/ Alan Fuhrman

Alan Fuhrman
Senior Vice President and 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, 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: November 15, 2004

/s/ Michael A. Martino

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, Alan Fuhrman, Senior Vice President and 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, 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: November 15, 2004

/s/ Alan Fuhrman

Alan Fuhrman
Senior Vice President and Chief Financial Officer