U.S. SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2005**

or

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

Commission file number 0-26866

Sonus Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**95-4343413**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes☐ No ☒

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

Class	**Outstanding at November 1, 2005**
Common Stock, $.001 par value	30,210,631

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Part I. Financial Information

Item 1. Financial Statements

Sonus Pharmaceuticals, Inc.
Balance Sheets

	September 30, 2005 (unaudited)	December 31, 2004
Assets		
Current assets:		
Cash and cash equivalents	$ 22,547,728	$ 416,847
Marketable securities	895,363	20,163,641
Other current assets	141,558	458,826
Total current assets	23,584,649	21,039,314
Equipment, furniture and leasehold improvements, net	1,108,245	1,479,785
Other assets	51,500	51,500
Total assets	$ 24,744,394	$ 22,570,599
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,493,295	$ 3,176,709
Current portion of lease obligations	26,736	78,445
Total current liabilities	5,520,031	3,255,154
Lease obligations, less current portion	21,873	42,172
Deferred rent	148,068	196,092
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; 26,301,142 and 21,352,795 shares issued and outstanding at September 30, 2005 and December 31, 2004, respectively	103,916,738	86,202,180
Accumulated deficit	(84,864,109)	(67,090,356)
Accumulated other comprehensive loss	1,793	(34,643)
Total stockholders' equity	19,054,422	19,077,181
Total liabilities and stockholders' equity	$ 24,744,394	$ 22,570,599

See accompanying notes.

Sonus Pharmaceuticals, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	7,978,606	2,401,403	13,970,920	7,629,657
General and administrative	1,063,596	1,290,853	4,102,232	3,493,657
Total operating expenses	9,042,202	3,692,256	18,073,152	11,123,314
Operating loss	(9,042,202)	(3,692,256)	(18,073,152)	(11,123,314)
Other income (expense):				
Other income	—	—	4,160	—
Interest income	135,856	84,904	300,901	192,080
Interest expense	(1,320)	(5,145)	(5,662)	(21,054)
Total other income, net	134,536	79,759	299,399	171,026
Loss before income taxes	(8,907,666)	(3,612,497)	(17,773,753)	(10,952,288)
Income taxes	—	—	—	—

Net loss	$ (8,907,666)	$ (3,612,497)	$ (17,773,753)	$ (10,952,288)
Basic and diluted net loss per share	$ (0.37)	$ (0.17)	$ (0.80)	$ (0.55)
Shares used in computation of basic and diluted net loss per share	23,831,912	21,312,949	22,187,457	19,776,375

See accompanying notes.

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

	Nine Months Ended September 30,	
	2005	2004
Operating activities:		
Net loss	$ (17,773,753)	$ (10,952,288)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	459,194	401,788
Noncash stock-based compensation	3,462	—
Accretion of net discount on marketable securities	(76,556)	(43,990)
Gain on sale of capital equipment	(4,160)	—
Changes in operating assets and liabilities:		
Other current assets	317,268	(114,332)
Accounts payable and accrued expenses	2,316,586	398,008
Other liabilities	(48,024)	(31,524)
Net cash used in operating activities	(14,805,983)	(10,342,338)
Investing activities:		
Purchases of capital equipment and leasehold improvements	(87,654)	(319,127)
Proceeds from sale of capital equipment	4,160	—
Purchases of marketable securities	—	(28,214,155)
Proceeds from sales of marketable securities	7,421,319	8,198,719
Proceeds from maturities of marketable securities	11,959,951	14,700,000
Net cash provided by (used in) investing activities	19,297,776	(5,634,563)
Financing activities:		
Proceeds from issuance of common stock under equity financings, net	16,645,583	14,440,667
Proceeds from exercise of common stock warrants	920,250	1,409,884
Proceeds from issuance of common stock under employee benefit plans	145,263	241,410
Payments on lease obligations	(72,008)	(112,162)
Net cash provided by financing activities	17,639,088	15,979,799
Increase in cash and cash equivalents for the period	22,130,881	2,898
Cash and cash equivalents at beginning of period	416,847	1,709,017
Total cash and cash equivalents	$ 22,547,728	$ 1,711,915
Supplemental cash flow information:		
Interest paid	$ 5,662	$ 21,054

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, 2004 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, 2004 and filed with the Securities and Exchange Commission on March 23, 2005. Certain prior year amounts have been reclassified to conform to the 2005 presentation.

2. Liquidity

The Company has historically experienced recurring losses from operations which have generated an accumulated deficit of $84.9 million through September 30, 2005. For the nine month period ended September 30, 2005, the Company used $14.8 million of cash to fund operations. At September 30, 2005, the Company had cash and cash equivalents and marketable securities of $23.4 million, and working capital of $18.1 million.

In August 2005, the Company raised approximately $16.6 million in net proceeds from a private equity financing agreement. Subsequent to the end of the third quarter, in October 2005, the Company executed a Collaboration and License Agreement with Schering AG ("Schering"). The agreement with Schering provides for (i) an upfront license fee of $20 million, (ii) product milestone payments of up to $132 million upon the achievement of certain U.S., European Union and Japanese clinical and regulatory milestones, (iii) sales milestone payments of up to $35 million upon the achievement of certain annual worldwide net sales, and (iv) upon commercialization, royalties ranging between 15-30% of annual net sales in the U.S., with the exact percentage to be determined based on the achievement of certain annual net sales thresholds, and royalties equal to 15% of the annual net sales outside the U.S. The parties have agreed to a development program consisting of the ongoing initial pivotal trial in metastatic breast cancer, trials to support the launch of TOCOSOL Paclitaxel and planned trials for additional indications, and have agreed to share equally in the costs of this development program. The Company has retained co-promotion rights in the U.S. and also granted Schering the right of first negotiation on the Camptothecin product currently in pre-clinical development at the Company. The effective date of the Collaboration and License Agreement and the payment of fees thereunder with Schering is subject toHart-Scott-Rodino regulatory clearance. In connection with the Collaboration and License Agreement, the Company entered into a Securities Purchase Agreement with Schering and Schering Berlin Venture Corporation ("SBVC"), whereby the Company issued and sold to SBVC 3,900,000 shares of common stock and a warrant to purchase 975,000 shares of common stock for aggregate consideration of $15.8 million. See Note 7.

The Company expects that its cash requirements will continue to increase in future periods due to the projected development costs associated with TOCOSOL Paclitaxel and other product candidates. However, the Company believes it has sufficient cash to fund operations through at least the end of 2006.

3. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	September 30, 2005	December 31, 2004
Accounts payable	$ 1,596,049	$ 815,203
Accrued expenses:		
Clinical trials	2,186,333	912,643
Compensation	730,362	792,755
Legal & professional	116,315	423,732
Product manufacturing/scale-up	602,856	40,500
Other	261,380	191,876
	$ 5,493,295	$ 3,176,709

4. Stockholders' Equity

In August 2005, the Company sold 4.7 million shares of common stock and warrants to purchase up to 2.3 million shares of common stock in a private placement transaction for gross proceeds of $17.8 million (approximately $16.6 million net of transaction costs). The common stock was sold at a price of $3.77 per share. The five-year warrants were sold at a price of $0.125 per share underlying each warrant, have an exercise price of $4.15 per share and expire in August 2010. This transaction constituted the only equity financing the Company has undertaken during the nine month period ended September 30, 2005.

During the third quarter of 2005, the Company recorded $920,000 in proceeds from the issuance of 225,000 shares of common stock from the exercise of common stock warrants. This was the only warrant exercise activity during the nine month period ended September 30, 2005. The Company also recorded $22,000 in proceeds from the issuance of 6,000 shares of common stock under employee benefit programs. During the nine month period ended September 30, 2005, the Company recorded $145,000 in proceeds from the issuance of 71,000 shares of common stock under employee benefit programs.

In October 2005, the Company issued 3,900,000 shares of common stock and warrants to purchase 975,000 shares of common stock to SBVC for aggregate consideration of $15.8 million in connection with the Collaboration and License Agreement with Schering. See Note 7.

5. Comprehensive Income (Loss)

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net loss	$ (8,907,666)	$ (3,612,497)	$ (17,773,753)	$ (10,952,288)
Unrealized gain (loss) on marketable securities	15,628	11,712	36,436	(24,496)
Comprehensive loss	$ (8,892,038)	$ (3,600,785)	$ (17,737,317)	$ (10,976,784)

6. Accounting for Stock Options

Under the provisions of Statement of Financial Accounting Standard (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. The Company has elected to follow the disclosure-only provisions of SFAS No. 123 and continue to apply APB 25 and related interpretations in accounting for its 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, 2005, the Company has 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 on options issued to employees.

As required under SFAS 123, the following table illustrates the effect on net loss and net loss per share if the Company 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,	
	2005	2004	2005	2004
Net loss, as reported	$ (8,907,666)	$ (3,612,497)	$ (17,773,750)	$ (10,952,288)

Add: Stock-based employee compensation expense included in reported net loss	—	—	3,462	—
Deduct: Stock-based employee compensation expense determined under the fair value based method	(385,498)	(342,277)	(1,242,618)	(1,205,565)
Pro forma net loss	$ (9,293,164)	$ (3,954,774)	$ (19,012,906)	$ (12,157,853)
Earnings per share:				
Basic and diluted-as reported	$ (0.37)	$ (0.17)	$ (0.80)	$ (0.55)
Basic and diluted-pro forma	$ (0.39)	$ (0.19)	$ (0.86)	$ (0.61)

The fair value of each stock 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 .8133 and 1.086 as of September 30, 2005 and 2004, respectively, and (6) a risk-free interest rate of 4.04% and 3.51% as of September 30, 2005 and 2004, respectively.

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, *Share Based Payment.* This statement is a revision to SFAS 123 and supersedes Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and amends FASB Statement No. 95, *Statement of Cash Flows.* This statement requires a public entity to expense the cost of employee services received in exchange for an award of equity instruments. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. This statement originally was effective for the first interim reporting period that begins after June 15, 2005 but the effective date was subsequently delayed by the Securities and Exchange Commission to January 1, 2006.

SFAS 123R permits public companies to choose between the following two adoption methods:

1. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date, or

2. A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, the Company generally recognizes no compensation cost for employee stock options. The impact of the adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future, although it is expected to generate significant additional expense for the Company. As the valuation of employee stock options under SFAS 123R is similar to SFAS 123, with minor exceptions, the adoption of SFAS 123R's fair value method will have a significant impact on the Company's results of operations, although it will have no impact on its overall financial position.

7. Subsequent Event

On October 17, 2005, the Company entered into a Collaboration and License Agreement with Schering AG, a German corporation, pursuant to which, among other things, the Company granted Schering an exclusive, worldwide license to its TOCOSOL Paclitaxel anti-cancer product (the "Product"). With respect to the Product, Schering will pay Sonus (i) an upfront license fee of $20 million, (ii) product milestone payments of up to $132 million upon the achievement of certain U.S., European Union and Japanese clinical and regulatory milestones, (iii) sales milestone payments of up to $35 million upon the achievement of certain annual worldwide net sales, and (iv) upon commercialization, royalties ranging between 15-30% of annual net sales in the U.S., with the exact percentage to be determined based on the achievement of certain annual net sales thresholds, and royalties equal to 15% of the annual net sales outside the U.S. The parties have agreed to a development program consisting of the ongoing initial pivotal trial in metastatic breast cancer, trials to support launch of the Product and planned trials for additional indications, and have agreed to share equally in the costs of this development program. The Company has retained co-promotion rights in the U.S. and also granted Schering the right of first negotiation on the Camptothecin molecule it is currently developing. The Collaboration and License Agreement is subject to Hart-Scott-Rodino regulatory clearance.

In connection with the Collaboration and License Agreement, the Company entered into a Securities Purchase Agreement with Schering and Schering Berlin Venture Corporation, a Delaware corporation ("SBVC" and collectively with Schering, the "Investors"), pursuant to which the Company sold an aggregate of 3,900,000 shares of common stock (the "Common Shares") and a warrant to purchase an aggregate of up to 975,000 shares of common stock (the "Warrant Shares" and collectively with the Common Shares, the "Shares"), resulting in aggregate consideration of approximately $15.8 million. The Common Shares were sold at $4.02 per share, which is equal to the per share closing price of the Company's common stock as reported on Nasdaq on October 14, 2005, the trading day immediately preceding the date of the Securities Purchase Agreement. The corresponding warrant was sold at a purchase price of $.125 multiplied by the number of Warrant Shares. The warrant has a five-year term and entitles its holder to purchase the Warrant Shares at an exercise price of $4.42 per share, which is equal to 110% of the purchase price per share of the common stock paid by the Investors under the Securities Purchase Agreement.

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:

- our anticipated future capital requirements and the terms of any capital financing agreements;
- timing and amount of future contractual payments, product revenue and operating expenses;
- progress and preliminary results of clinical trials;
- anticipated regulatory filings, requirements and future clinical trials; and
- market acceptance of our products and the estimated potential size of these markets.

While these forward-looking statements made by us are based on our current beliefs and judgments, they are subject to risks and uncertainties that could cause actual

results to vary from the projections in the forward-looking statements. You should consider the risks below carefully in addition to other information contained in this report 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:

- future capital requirements and uncertainty of payments under corporate partnerships or additional funding through either debt or equity financings;
- uncertainty of governmental regulatory requirements and lengthy approval process;
- dependence on the development and commercialization of products;
- future prospects heavily dependent on results of the Phase 3 trial for TOCOSOL Paclitaxel and subsequent commercialization should the product be approved by the FDA;
- history of operating losses and uncertainty of future financial results;
- dependence on third parties for funding, clinical development, manufacturing and distribution;
- dependence on key employees;
- uncertainty of U.S. or international legislative or administrative actions;
- competition and risk of competitive new products;
- 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;
- continued listing on the Nasdaq National Market;
- potential for product liability issues and related litigation;
- potential for claims arising from the use of hazardous materials in our business; and
- volatility in the value of our common stock.

MD&A Overview

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

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

Business Overview

Sonus Pharmaceuticals is focused on the development of therapeutic drugs that may offer improved effectiveness, safety, tolerability and administration for the treatment of cancer and related conditions. Our business strategy is as follows:

- Develop proprietary formulations of therapeutic drugs utilizing our TOCOSOL® technology platform; and

- Identify and acquire products/technologies that are complementary to our focus in oncology and related fields in order to broaden our business and market opportunities.

TOCOSOL Technology Platform

Our proprietary TOCOSOL technology platform has been designed to address the challenges of hard-to-formulate cancer drugs. Development of drugs with our TOCOSOL technology may result in products with equivalent or better efficacy, decreased incidences of side effects and improved dosing convenience. The TOCOSOL technology uses vitamin E oil (a-tocopherol) and tocopherol derivatives to solubilize and stabilize drugs, making them easier to formulate and deliver into the body.

TOCOSOL Paclitaxel

Our lead oncology candidate, 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 formulation. We believe that data from our clinical trials conducted to date suggest that TOCOSOL Paclitaxel compares favorably with approved taxane products and other new paclitaxel formulations under development (safety and efficacy remain to be proven in Phase 3 testing); 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 Taxotere® and Taxol or generic versions of paclitaxel; does not require any special intravenous, or IV tubing, filters or other apparatus; and does not require reconstitution or dilution, which results in administration of small volumes of 15 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 in this study 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 RECIST, partial response is defined as

reduction in the sum of the longest tumor dimensions of target lesions of ³30% for at least four weeks, and no evidence of progressive disease elsewhere). Dose-limiting toxicities included myalgia (muscle aches), fatigue, and neutropenia (low neutrophilic white blood cell count). No Grade 4 neuropathy (damage to the peripheral nerves) was seen at or below the estimated MTD 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 were single agent, open label studies that enrolled patients who had progressive disease despite prior treatment with one standard chemotherapy regimen, but who had not previously received taxane chemotherapy. Each Phase 2a study began with a dose escalation phase to estimate the best tolerated dose of TOCOSOL Paclitaxel using weekly administration. The best tolerated dose was initially estimated to be 120 mg/m² per week in the ovarian and lung cancer trials, and 100 mg/m² per week in the bladder cancer trial, based on observations among a small number of patients treated for a few weeks. However, subsequent retrospective review of actual doses administered across all patients in all studies over extended treatment periods has suggested that patients assigned to receive weekly doses of 100 mg/m² or 120 mg/m² actually received similar cumulative doses over time, based on long-term tolerability.

Patient enrollment in the Phase 2a clinical trials was completed in the second quarter of 2003, and all patients have been evaluated by their physicians for efficacy results. Data review, confirmation and analysis are ongoing, and databases have not yet been locked. A total of 120 patients in the ovarian, non-small cell lung and bladder cancer studies were evaluable for objective response, which means that the patients received at least eight weekly cycles of TOCOSOL Paclitaxel and had at least one CT scan to confirm anti-tumor responses according to RECIST.

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 RECIST, 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 (stable disease is defined as less than a 30% decrease and no more than a 20% increase in the sum of the longest tumor diameters per RECIST). Using a 95% confidence interval, the investigator reported objective response rate of 39% could range from 26% to 54%.

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. Using a 95% confidence interval, the investigator reported objective response rate of 21% could range from 10% to 37%.

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. Using a 95% confidence interval, the investigator reported objective response rate of 33% could range from 17% to 54%.

The investigator-reported response rates for these three clinical trials are summarized in the table below:

Cancer Type	No. Patients Evaluable	Stable Disease	Objective Responses (OR)				
			Partial Response	Complete Response	Total OR	% OR	95% CI
Ovarian	51	16	17	3	20	39%	(26% - 54%)
NSCL	42	18	6	3	9	21%	(10% - 37%)
Bladder	27	11	7	2	9	33%	(17% - 54%)

Following completion of treatment, follow-up monitoring of each consenting patient was continued to assess survival duration. Median survival in each of the three studies has been estimated based on reports received from investigators as of May 2005:

Cancer Type	Median Survival (wks)	95% CI (wks)
Ovarian	73.9	(49.1 - 116.4)
NSCL	34.7	(18.9 - 48.0)
Bladder	57.4	(27.1 - 94.9)

In September 2004, we initiated a Phase 2b study of TOCOSOL Paclitaxel for first line treatment of women with metastatic breast cancer. By October 2004, we had enrolled a total of 47 patients. At the end of September 2005, the investigators reported an overall objective response rate of53%, with a 95% confidence interval of 38% to 68%. Review of all radiographic images by an independent radiologist who had no information about patients' treatment or non-radiographic assessments reported a confirmed objective response rate of 49%, with a 95% confidence interval of 34% to 64%. Nine patients remained on active treatment at the end of September 2005. We expect to be able to estimate the median time to disease progression this year and follow-up for survival will continue throughout the next two years.

In addition to being assessed for anti-tumor efficacy, patients are also monitored for adverse events in clinical studies. The most significant adverse events expected with taxanes are neutropenia and peripheral neuropathy. The incidence of Grade 3 or Grade 4 neutropenia across the Phase 2 studies (197 patients) was 42%. Among 197 patients treated in the Phase 2 clinical trials, the incidence of at least one episode of Grade 4 neutropenia (absolute neutrophil count <500 cells/mm3) during treatment was 18%. However, only 2% of patients had febrile neutropenia, and there were no septic deaths. No peripheral neuropathy was observed in 53% of patients, Grade 3 peripheral neuropathy was reported in only 12% of patients, and no patients experienced Grade 4 peripheral neuropathy. We believe these adverse event rates compare favorably to the reported neutropenia and peripheral neuropathy experienced when Taxol is administered at the approved dose of 175 mg/m^2 every three weeks. Dose reductions or treatment delays due to toxicity from TOCOSOL Paclitaxel did not limit long-term treatment in most patients. Paclitaxel-mediated infusion reactions, sometimes called "hypersensitivity reactions" and involving pain, flushing, shortness of breath or chest tightness, were infrequently observed following more than 2,500 administered doses. Investigators have reported that infusion reactions with our product could be ameliorated by temporary (a few minutes) interruption of infusion, while corticosteroid premedications were not helpful. Infusion reactions very rarely prevented delivery of intended doses. Overall, we believe that TOCOSOL Paclitaxel appears to be well tolerated over multiple treatment cycles.

The results of the Phase 2a and 2b clinical trials are preliminary at this time and have not been independently verified by masked radiologists and may or may not be indicative of the final results upon completion of the these studies or of the results of our planned Phase 3 study that was initiated in September 2005.

The manufacturing process for TOCOSOL Paclitaxel has been successfully scaled to support commercialization. In March 2005, Sonus met with the U.S. Food and Drug Administration ("FDA") to discuss the Chemistry, Manufacturing and Controls ("CMC") data for the drug product. The FDA did not identify any issues with the manufacture and control of the drug product that would preclude Sonus from using TOCOSOL Paclitaxel in the Phase 3 trial.

Our objective is to work with our collaborative partner (Schering) to advance the final clinical development, gain marketing approval and then maximize the commercial opportunity of TOCOSOL Paclitaxel. We have outlined a regulatory strategy for TOCOSOL Paclitaxel that includes three potential 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 the following:

- *505(b)(2).* We will seek initial approval of TOCOSOL Paclitaxel with a 505(b)(2) NDA submission, which will rely on the FDA's previous findings of safety and efficacy for Taxol (the reference paclitaxel product), supplemented by data supporting TOCOSOL Paclitaxel's safety and efficacy. The FDA's use of the 505(b)(2) mechanism is designed to streamline the NDA review process by not requiring duplicate work for active pharmaceutical ingredients that are already well known. As part of our regulatory strategy, we initiated a randomized crossover clinical pharmacology study in the fourth quarter of 2003, to compare the amount of paclitaxel delivered into circulation over time by TOCOSOL Paclitaxel and Taxol, with both drugs given at 175 mg/m^2 every three weeks (the approved dosing regimen for Taxol). We completed patient enrollment in March 2004 and final data were available for analysis in September 2004. The data from this study indicate that TOCOSOL Paclitaxel delivers 67% higher exposure to free (unbound) paclitaxel, and 108% higher exposure to total (protein-bound and unbound) paclitaxel than an equal dose of Taxol. How this may or may not correlate to the efficacy of TOCOSOL Paclitaxel as compared to Taxol is yet to be proven in Phase 3 clinical testing. Sonus met with the FDA in December 2004, and based on preclinical and clinical data generated to date, the FDA indicated that it was appropriate for Sonus to pursue a single Phase 3 clinical trial that would lead to submission of a NDA for TOCOSOL Paclitaxel under the 505(b)(2) regulatory mechanism. The FDA and Sonus agreed to finalize the study design and plan for conducting and analyzing the results of the Phase 3 trial under a Special Protocol Assessment ("SPA"). The SPA process began early in 2005, and was completed in June 2005. The approved study is designed to compare the safety and efficacy of TOCOSOL Paclitaxel administered weekly as compared to Taxol administered weekly.

  Based on agreement from the FDA on the use of a single Phase 3 trial in our TOCOSOL Paclitaxel NDA, we believe that the NDA, based on a primary endpoint of objective response rate, could be submitted within 12 months after the completion of patient enrollment into the Phase 3 study, which we believe will take approximately 6-12 months. We believe that submission of our NDA is likely to occur in 2007. The FDA has indicated to Sonus that approval under 505(b)(2) will require either (i) demonstration of superiority of TOCOSOL Paclitaxel as compared to Taxol, if the Taxol dosing regimen used differs from the approved label at the time of the NDA filing by the FDA; (ii) a change of the approved label for Taxol and/or generic equivalents to include a weekly dosing schedule by the time of the NDA filing by the FDA; or (iii) submission of reviewable data from a Phase 3 trial using Taxol on a weekly dosing schedule, as compared to Taxol using the currently approved three-weekly dosing schedule. We do not currently believe that the timing or cost of the Phase 3 trial or the NDA submission will be materially adversely affected by these requirements. The clinical trial protocol and Statistical Analysis Plan approved under

the SPA provide for a nested superiority analysis of TOCOSOL Paclitaxel compared to Taxol, provided that we first demonstrate non-inferiority; however, there can be no assurance that the Phase 3 clinical trial data will demonstrate that TOCOSOL Paclitaxel is non-inferior or superior to Taxol. Further, there can be no assurance that the approved label for Taxol or generics will be changed to provide for weekly dosing, although we do believe, based on repeated discussions with the FDA, that they are pursuing this change. Large Phase 3 clinical trials by third parties have been conducted utilizing Taxol on a weekly versus a three-weekly basis. However, there can be no assurance that Sonus will have right of reference to the data from such trials. If Sonus is required to conduct an additional Phase 3 trial of Taxol weekly versus three-weekly, substantial additional costs and time would be required before the NDA submission for TOCOSOL Paclitaxel.

- *New indication for taxanes.* Under this component of our regulatory strategy, we will pursue approval for the use of TOCOSOL Paclitaxel as a treatment for inoperable or metastatic urothelial transitional cell cancers (mostly urinary bladder cancers), an indication for which there is an unmet medical need for an 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. during the fourth quarter of 2003 using weekly dosing of TOCOSOL Paclitaxel. Enrollment in this trial has been challenging due to the limited population of patients in this indication and the inconsistent standard of treatment for it. Additional study sites in Europe have recently been opened to augment enrollment in this trial. In December 2004, the FDA also granted an Orphan Drug designation to TOCOSOL Paclitaxel for the treatment of non-superficial urothelial cancer.

- *Life cycle management.* With this component of our regulatory strategy, we intend to conduct trials in other types of cancer, 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. The data from such clinical trials could support supplements to the NDA following a 505(b)(2) NDA, if approved.

The scope, timing and costs of the clinical trials to be conducted under all of the above regulatory strategies are difficult to determine with accuracy. We are pursuing a single pivotal Phase 3 trial in metastatic breast cancer, an indication where Paclitaxel is approved, with a primary endpoint of objective response rate and secondary endpoints of progression-free survival and overall survival durations. We expect to submit the NDA with data on the primary endpoint, potentially followed by supplemental applications when data are mature for the secondary endpoints. The Phase 3 trial, which compares TOCOSOL Paclitaxel to Taxol administered weekly, is powered to achieve statistical significance on all three endpoints, and is expected to enroll approximately 800 evaluable patients. Under our Collaboration and License Agreement dated October 17, 2005 with Schering, they have agreed to fund 50% of these costs. In addition to the supportive trials Sonus plans to conduct, it is anticipated that we will collaborate with Schering on additional studies for TOCOSOL Paclitaxel. Under the terms of the Collaboration and License Agreement with Schering, we are also obligated to fund 50% of the costs of certain studies conducted by Schering. The exact cost and timing of these studies is yet to be finalized. Should our clinical data support an NDA submission based on the primary endpoint of objective response rate, we anticipate that the NDA could be submitted within 12 months after conclusion of patient enrollment. This trial will constitute the bulk of the Company's clinical trial

spending in the near term, and at least half the cost of the Phase 3 trial is anticipated to occur in the first 12 months after the start of the study. However, these costs may vary significantly depending upon regulatory and other matters that are not within our control and there can be no assurance that such amount will be sufficient to complete the study. There can be no assurance that the results of any or all of the anticipated clinical trials will be successful or will support an approved product.

Research and Development Pipeline

We continue to invest in the research and development of new product candidates, including those that we believe could extend the application of our TOCOSOL technology platform. We are currently evaluating early stage therapeutic drug formulations utilizing the TOCOSOL technology, including potential product candidates based on the camptothecin class of molecules. The camptothecin molecule family is poorly soluble and difficult to formulate. 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 camptothecin 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 development candidates into human clinical trials is dependent on several factors including technological feasibility and commercial opportunity as well as the availability of financial resources.

In addition to our internal research and development efforts, we may also consider other acquisitions of complementary products, development candidates or technologies to expand our pipeline and capabilities.

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 selected 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, 2005, we hold seven United States patents and three patents issued in other countries, one in Canada, one in Taiwan and one in India, pertaining to our TOCOSOL technology platform. We hold one additional United States patent directed to 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 September 30, 2005, our accumulated deficit was approximately $84.9 million. We expect to incur substantial additional operating losses over the next several years. Such losses have been and will continue to principally be the result of various costs associated with our discovery and research and development programs. 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. Our ability to achieve a consistent, profitable level of operations depends in large part on obtaining regulatory approval for TOCOSOL Paclitaxel as well as future product candidates in addition to successfully manufacturing and marketing those 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.

We had no revenue for the three and nine month periods ended September 30, 2005 and 2004, respectively.

Our research and development (R&D) expenses were $8.0 million for the three months ended September 30, 2005 compared with $2.4 million for the same period in 2004. Our R&D expenses were $14.0 million for the nine months ended September 30, 2005 compared with $7.6 million for the same period in 2004. The increase for the three and nine month periods ended September 30, 2005 was primarily attributable to pre-initiation, control and study drug costs related to our Phase 3 pivotal trial for TOCOSOL Paclitaxel and its continued development as well as development costs associated with product candidates in our pipeline and increased cost for personnel. We expect R&D expenses to continue to increase substantially as our Phase 3 clinical trial for TOCOSOL Paclitaxel begins to enroll significant numbers of patients.

Our general and administrative (G&A) expenses were $1.1 million for the three months ended September 30, 2005 compared with $1.3 million for the same period in 2004. Our G&A expenses were $4.1 million for the nine months ended September 30, 2005 compared with $3.5 million for the same period in 2004. The decrease for the three month period ended September 30, 2005 was primarily due to higher consulting costs in 2004 for Sarbanes-Oxley compliance and market research activities. The increase for the nine month period ended September 30, 2005 was primarily attributable to increased legal, business development and personnel costs in 2005. G&A expenses for the remainder of 2005 are expected to remain relatively flat compared to the third quarter of 2005.

Our total operating expenses for the balance of 2005 are expected to increase substantially from those experienced in the first nine months of 2005 as we continue to spend on the Phase 3 clinical development of TOCOSOL Paclitaxel. We estimate that R&D spending will comprise approximately 80%-85% of the anticipated spending in the fourth quarter of 2005 as well as 2006. A significant portion of the R&D spending will be devoted to the Phase 3 clinical trial for TOCOSOL Paclitaxel. These estimates and actual expenses are subject to change depending on many factors, including unforeseen expansion of study size or duration, complications in conducting or completing studies when the study begins, changes in FDA requirements, increased material costs and other factors.

Our other income, net was $135,000 for the three months ended September 30, 2005 compared with $80,000 for the same period in 2004. Our other income, net was $299,000 for the nine months ended September 30, 2005 compared with $171,000 for the same period in 2004. The 2005 increases were due primarily to higher interest rates in 2005.

We had no income tax expense in the three and nine month periods ended, September 30, 2005 or the same period in 2004 as we have incurred significant losses and have significant net operating loss carryforwards.

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, 2005, we had cash, cash equivalents and marketable securities totaling $23.4 million compared to $20.6 million at December 31, 2004. The increase was primarily due to the $16.6 million in net proceeds from the private placement of 4.7 million shares of common stock and common stock warrants in August 2005, $920,000 in proceeds from the issuance of 225,000 shares of common stock from the exercise of common stock warrants and $145,000 in proceeds from the issuance of 71,000 shares of common stock under employee benefit programs. The balance of the increase was primarily due to timing of payments for accounts payable and accrued expenses largely related to the Phase 3 pivotal trial for TOCOSOL Paclitaxel and the proceeds from sales and maturities of marketable securities. These increases were offset in part by the net loss for nine months ended September 30, 2005 of $17.8 million.

Net cash used in operating activities for the nine months ended September 30, 2005, and 2004, was $14.8 million and $10.3 million, respectively. Expenditures in all periods were a result of R&D expenses, including clinical trial costs, and G&A expenses in support of our operations and product development activities primarily related to TOCOSOL Paclitaxel and to a lesser extent other potential product candidates. G&A expenses for the remainder of 2005 are expected to remain relatively flat compared to the third quarter of 2005. Our R&D expenses are dependent upon the scope of our clinical trial activities but are expected to continue to increase substantially as we begin to enroll significant numbers of patients in the Phase 3 clinical trial for TOCOSOL Paclitaxel. We recognized no revenues in either of the periods presented and paid no corporate income taxes.

Net cash provided by (used in) investing activities for the nine months ended September 30, 2005 and 2004 was $19.3 million and ($5.6 million), respectively. The cash provided by investing activities in 2005 was primarily related to maturities and sales of marketable securities occurring in the normal course of business. The cash used in investing activities in 2004 was primarily related to purchases of short-term investments and purchases of property and equipment, offset in part by maturities and sales of marketable securities occurring in the normal course of business. Activity related to short-term marketable securities related primarily to the investment of money raised in equity financings and the related maturities and sales of those investments recorded accordingly to provide working capital to us on an as needed basis.

Net cash provided by financing activities for the nine months ended September 30, 2005, and 2004 was $17.6 million and $16.0 million, respectively. The net cash provided by financing activities in 2005 primarily related to the proceeds from the August 2005 equity financing, proceeds from the exercise of common stock warrants and the issuance of common stock under employee benefit plans. The net cash provided by financing activities in 2004 primarily related to proceeds from an equity financing, proceeds from the exercise of common stock warrants and the issuance of common stock under employee benefit plans.

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. We believe that existing cash and marketable securities, in addition to payments pending and cost sharing arrangements under our Collaboration and License Agreement with Schering, will be sufficient to fund operations through at least the end of 2006. In addition to the supportive trials Sonus plans to conduct, it is anticipated that we will

collaborate with Schering on additional studies. Under the terms of the Collaboration and License Agreement with Schering, we are also obligated to fund 50% of the costs of certain studies conducted by Schering. The exact cost and timing of these studies is yet to be finalized. However, the scope, timing and costs of the Phase 3 clinical trial are difficult to determine with accuracy and these costs may vary significantly depending upon regulatory and other matters that are not within our control. We will need additional capital in 2007 to support the continued development of TOCOSOL Paclitaxel, our obligations under the Collaboration and License Agreement with Schering and to fund continuing operations. Should our clinical data support an NDA submission based on the primary endpoint of objective response rate, we anticipate that the NDA could be submitted within 12 months after conclusion of patient enrollment. Our future capital requirements depend on many factors including:

- our ability to obtain and timing of payments, under corporate partner agreements and/or debt or equity financings;
- timing and costs of preclinical development, clinical trials and regulatory approvals;
- timing and amount of costs to support our obligations under the Collaboration and License Agreement with Schering;
- drug discovery and research and development;
- entering into new collaborative or product license agreements for products in our pipeline;
- timing and costs of technology transfer associated with manufacturing and supply agreements; and
- costs related to obtaining, defending and enforcing patents.

We have contractual obligations in the form of operating leases and leasehold financing arrangements. We have remaining contractual obligations through 2007 under our operating leases of $1.3 million and $53,000 under our leasehold financing agreements. This does not include our obligations under the Collaboration and License Agreement with Schering which are yet to be finalized. The following table summarizes our contractual obligations under these agreements, including interest as of September 30, 2005:

Contractual Obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Lease financing obligations	$ 53,188	$ 30,393	$ 22,795	$ —	$ —
Operating lease obligations	1,318,070	701,052	617,018	—	—
Total	$ 1,371,258	$ 731,445	$ 639,813	$ —	$ —

Critical Accounting Policies and Estimates

- *Cash and Cash Equivalents.* We consider investments in highly liquid instruments purchased with a remaining maturity of 90 days or less to be cash equivalents. The amounts are recorded at cost, which approximate fair market value. Our cash equivalents and marketable securities consist principally of commercial paper, money market securities, corporate bonds/notes and government agency securities. We have classified our entire investment portfolio as available-for-sale. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a separate component of stockholders' equity and included in accumulated other comprehensive income. The amortized cost of investments is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Interest earned on securities is included in interest income. We consider marketable securities with maturity greater than 12 months long-term and maturity less than 12 months short-term.

- *Revenue Recognition.* Since inception, we have generated revenue from collaborative agreements, licensing fees and from the assignment of developed and patented technology. We have recognized this revenue primarily through up-front, milestone and licensing payments. We recognize license revenue from intellectual property agreements. Generally, the payments received under these research collaboration agreements are contractually not refundable even if the research effort is not successful. Performance under our collaborative agreements is measured by scientific progress, as mutually agreed upon by us and our collaborators.

  Up-front Payments: Up-front payments from our research collaborations include payments for technology transfer and access rights. Non-refundable, up-front payments received in connection with collaborative research and development agreements are deferred and recognized on a straight-line basis over the relevant periods specified in the agreement, generally the research term. When the research term is not specified in the agreement and instead the agreement specifies the completion or attainment of a particular development goal, an estimate is made of the time required to achieve that goal considering experience with similar projects, level of effort and the development stage of the project. The basis of the revenue recognition is reviewed and adjusted based on the status of the project against the estimated timeline as additional information becomes available.

  Milestones: Payments for milestones that are based on the achievement of substantive and at risk-performance criteria are recognized in full at such time as the specified milestone has been achieved according to the terms of the agreement. When payments are not for substantive and at-risk milestones revenue is recognized as if the payment was an up-front fee.

  License Fees: Non-refundable license fees where we have completed all future obligations are recognized as revenue in the period when persuasive evidence of an agreement exists, delivery has occurred, collectability is reasonably assured and the price is fixed and determinable.

  Royalty Income: Royalties from licensees are based on reported sales of licensed products and revenue is calculated based on contract terms when reported sales are reliably measurable and collectability is reasonably assured.

- *Research and Development Expenses.* Pursuant to SFAS No. 2, *Accounting for Research and Development Costs*, our research and development costs are expensed as incurred. In instances where we enter 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. Research and development expenses include, but are not limited to, payroll and personnel expenses, lab expenses, clinical trial and related clinical manufacturing costs, facilities and overhead costs.

- *Use of Estimates.* Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been

prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent liabilities. In preparing these financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, marketable securities, income taxes, clinical trials, and other contingencies. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results could differ from these estimates.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, *Share Based Payment.* This statement is a revision to SFAS 123 and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows.* This statement requires a public entity to expense the cost of employee services received in exchange for an award of equity instruments. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. This statement originally was effective for the first interim reporting period that begins after June 15, 2005 but the effective date was subsequently delayed by the Securities and Exchange Commission to January 1, 2006.

SFAS 123R permits public companies to choose between the following two adoption methods:

2. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date, or

2. A "modified retrospective" method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, the Company generally recognizes no compensation cost for employee stock options. The impact of the adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future, although it is expected to generate significant additional expense for the Company. As the valuation of employee stock options under SFAS 123R is similar to SFAS 123, with minor exceptions, the adoption of SFAS 123R's fair value method will have a significant impact on the Company's results of operations, although it will have no impact on its overall financial position.

Certain Factors That May Affect Our Business and Future Results

We will need additional capital in the future, and if it is not available on terms acceptable to us, or at all, we would have to scale back our expenditures, development and commercialization activities as well as reduce personnel costs.

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. We estimate that existing cash, cash equivalents and marketable securities, in addition to payments pending and cost sharing arrangements under our Collaboration and License Agreement with Schering, will be sufficient to fund operations through at least the end of 2006. We will need additional capital to complete the development of TOCOSOL Paclitaxel, fund our obligations under the collaborative license agreement with Schering, fund the development of other product candidates and support our continuing operations. In addition to the supportive trials Sonus plans to conduct, it is anticipated that we will collaborate with Schering on additional studies. Under the terms of the Collaboration and License Agreement with Schering, we are also obligated to fund 50% of the costs of certain studies conducted by Schering. The exact cost and timing of these studies is yet to be finalized. However, the scope, timing and costs of the Phase 3 clinical trial are difficult to determine with accuracy and these costs may vary significantly depending upon regulatory and other matters that are not within our control. Should our clinical data support an NDA submission based on the primary endpoint of objective response rate, we anticipate that the NDA could be submitted within 12 months after conclusion of patient enrollment. Our future capital requirements depend on many factors including:

- our ability to obtain and timing of payments, under corporate partner agreements or other financing;
- timing and costs of preclinical development, clinical trials and regulatory approvals;
- timing and amount of costs to support our obligations under the Collaboration and License Agreement with Schering;
- entering into new collaborative or product license agreements;
- timing and costs of technology transfer associated with manufacturing and supply agreements; and
- costs related to obtaining, defending and enforcing patents.

Any future debt or 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 2007, we will have to reduce our expenditures and scale back the development of our products and new product research and development. In addition, we may not be able to fund our obligations under the Collaboration and License Agreement with Schering, in which case we could be in default under the agreement which could cause us to incur penalties or the agreement to be terminated.

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 product candidates are subject to significant uncertainty because they are in both early to late 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 effect on our business, financial condition and results of operations. In June 2005, the FDA completed its review of the contents of the SPA for TOCOSOL Paclitaxel. The FDA has indicated to Sonus that approval under 505(b)(2) will require either (i) demonstration of superiority of TOCOSOL Paclitaxel as

compared to Taxol, if the Taxol dosing regimen used differs from the approved label at the time of the NDA filing by the FDA; (ii) a change of the approved label for Taxol and/or generic equivalents to include a weekly dosing schedule by the time of the NDA filing by the FDA; or (iii) submission of reviewable data from a Phase 3 trial using Taxol on a weekly dosing schedule, as compared to Taxol using the currently approved three-weekly dosing schedule. We do not currently believe that the timing or cost of the Phase 3 trial or the NDA submission will be materially adversely affected by these requirements. The clinical trial protocol and Statistical Analysis Plan approved under the SPA provide for a nested superiority analysis of TOCOSOL Paclitaxel compared to Taxol, provided that we first demonstrate non-inferiority; however, there can be no assurance that the Phase 3 clinical trial data will demonstrate that TOCOSOL Paclitaxel is non-inferior or superior to Taxol. Further, there can be no assurance that the approved label for Taxol or generics will be changed to provide for weekly dosing, although we do believe, based on repeated discussions with FDA, that they are pursuing this change. Large Phase 3 clinical trials by third parties have been conducted utilizing Taxol on a weekly versus a three-weekly basis. However, there can be no assurance that Sonus will have right of reference to the data from such trials. If Sonus is required to conduct an additional Phase 3 trial of Taxol weekly versus three-weekly, substantial additional costs and time would be required before the NDA submission for TOCOSOL Paclitaxel. In addition, there is pending litigation attacking the utilization of the 505(b)(2) regulatory strategy generally. There can be no assurance that such litigation will not be successful. A 505(b)(2) application permits us to rely upon the FDA's findings of safety and efficacy for a previously approved drug product without requiring us to obtain a right of reference from the original applicant. In addition to permitting reliance upon the FDA's prior findings of safety and effectiveness for previously approved drugs, section 505(b)(2) continues to allow reliance on third party data that is available in published literature and which establishes the safety and effectiveness of a drug. However, we are required to provide any additional clinical data necessary to demonstrate the safety and effectiveness of differences between the original drug and the 505(b)(2) drug, so while unnecessary duplication of preclinical and certain human studies is avoided, specific studies may be required to establish the relevance and applicability of prior findings for our particular product formulation. We cannot predict if or when any of our products under development will be commercialized.

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 TOCOSOL technology platform. Most of our attention and resources are directed to the development of TOCOSOL, a 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 incur

additional losses, our accumulated deficit will increase and our business 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.

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, 2005, our accumulated deficit totaled $84.9 million. We anticipate that our operating losses will continue as we further invest in research and development for our products. We will not generate the majority of milestone or royalty revenues under our collaboration and license agreement with Schering unless and until we receive regulatory approval, which is not likely to occur until 2008. Even if we generate milestone and royalty 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 of payments, under our Collaboration and License Agreement with Schering or our ability to obtain other corporate partner agreements or other financing;
- timing and costs of preclinical development, clinical trials and regulatory approvals;
- timing and amount of costs to support our obligations under the Collaboration and License Agreement with Schering;
- drug discovery and research and development;
- timing and costs of technology transfer associated with manufacturing and supply agreements; and
- costs related to obtaining, defending and enforcing patents.

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 executed an agreement with Schering for TOCOSOL Paclitaxel in October 2005. This agreement is subject to Hart-Scott-Rodino regulatory clearance. Under the Collaboration and License Agreement, Schering is responsible for clinical development and regulatory activities outside of the U.S. If these arrangements with third parties are terminated or the collaborations are not successful, we will be required to identify alternative sources of funding to finance research, clinical development, manufacturing, marketing, sales and/or distribution. Our inability to secure additional funding would 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 our partners 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.

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, including Michael A. Martino, President & Chief Executive Officer, Michael B. Stewart, Senior Vice President & Chief Medical Officer and Alan Fuhrman, Senior Vice President & Chief Financial Officer. We do not have employment agreements in place with these key executives nor do we maintain any key person life insurance coverage on these persons. 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. On January 7, 2005, American Pharmaceutical Partners obtained FDA approval to market its paclitaxel-based product, ABRAXANE™ (paclitaxel protein-bound particles for injectible suspension). 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 even if 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 product candidates. 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. TEVA Pharmaceuticals USA (TEVA) is our primary manufacturer of TOCOSOL Paclitaxel for clinical studies and has also agreed to manufacture TOCOSOL Paclitaxel for commercialization. The TEVA agreement has an initial term of five years after market introduction of TOCOSOL Paclitaxel, provided that market introduction occurs before June 2009, and is not terminable at will. 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. GMP are enumerated in FDA regulations and guidance documents. The facilities, procedures, and operations of our contract manufacturers must be determined to be adequate by the FDA before approval of product manufacturing. Manufacturing facilities are subject to inspections by the FDA for compliance with GMP, licensing specifications, and other FDA regulations. Failure to comply with FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of NDAs, injunctions and criminal prosecution. Any of these actions could have a material adverse effect on us. 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, 2005, we held seven United States patents and three patents issued in other countries, one in Canada, one in Taiwan and one in India pertaining to our TOCOSOL technology platform. We hold one additional United States patent directed to 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 could result in the termination of the Collaboration and License Agreement with Schering and 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. We currently maintain product liability insurance for our clinical trials with limits of $10 million per claim and in the aggregate, which we believe to be adequate for current non-commercial and Phase 3 applications of our products. 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 $1.00 per share and a market value of our public float of at least $15.0 million. As of September 30, 2005, we had stockholders' equity of approximately $19.1 million. In the event that we fail to satisfy the listing standards on a continuous basis, our common stock may be removed from listing on The Nasdaq National Market. If our common stock were delisted from The Nasdaq National Market, our common stock may be transferred to the Nasdaq SmallCap Market if we satisfy the listing criteria for the Nasdaq SmallCap Market or trading of our common stock, if any, may be conducted in the over-the-counter market in the so-called "pink sheets" or, if available, the 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, 2005, 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

Evaluation of disclosure 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 them to material information required to be included in our periodic SEC filings. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls are met, and no evaluation of controls can provide absolute assurance that all controls and instances of fraud, if any, within a company have been detected.

Changes in internal control over financial reporting

We have not made any significant changes to our internal control over financial reporting (as defined in rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Items 1, 3, 4 and 5 are not applicable and have been omitted.

Item 2. Changes in Securities and Use of Proceeds

In August 2004, Sonus sold 4,651,869 shares of its common stock for a purchase price of $3.77 per share and warrants to purchase up to 2,325,936 shares of its common stock for a purchase price per warrant of $.125 per share underlying each warrant. The warrants are exercisable at any time prior to August 2010 at an exercise price of $4.15 per share. The aggregate purchase price of the common stock and warrants to purchase common stock was approximately $17.8 million, resulting in net proceeds to Sonus of approximately $16.6 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 and shares of common stock issuable upon exercise of the warrants sold in the offering. This registration statement was declared effective by the Securities and Exchange Commission in September 2005. The shares of common stock and warrants to purchase common stock were sold to new and current institutional and accredited investors in conformity with rule 506 under Regulation D and under Section 4(2) of the Securities Act. Each of the investors represented such investor's intention to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the instruments representing the common stock and warrants issued by Sonus. The offering was conducted without any general solicitation or advertising.

Item 6. Exhibits

(a) Exhibits

31.1 Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a).

31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a).

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

32.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b).

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 9, 2005

By: /s/ Alan Fuhrman
Alan Fuhrman
Senior Vice President,
Chief Financial Officer
(Principal Financial 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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 9, 2005

/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 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 report;

3. Based on my knowledge, the financial statements, and other financial information included in this 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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) 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

   (d) 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 9, 2005

/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, 2005 (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 9, 2005

/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, 2005 (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 9, 2005

/s/ Alan Fuhrman
Alan Fuhrman
Senior Vice President and Chief
Financial Officer