

# 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 MARCH 31, 2006**

or

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

Commission file number 0-26866

### Sonus Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**95-4343413**  
(I.R.S. Employer Identification Number)

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

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 May 4, 2006
Common Stock, \$.001 par value	36,782,764

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Items 1, 2, 3, 4 and 5 are not applicable and therefore have been omitted.

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

	<u>March 31, 2006</u>	<u>December 31, 2005</u>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 48,226,345	\$ 49,317,845
Accounts receivable from Schering AG	3,473,530	7,056,640
Other current assets	333,001	341,787
Total current assets	<u>52,032,876</u>	<u>56,716,272</u>
Equipment, furniture and leasehold improvements, net	929,539	1,006,403
Long term receivable from Schering AG	87,500	87,500
Other assets	<u>95,903</u>	<u>103,739</u>
Total assets	<u>\$ 53,145,818</u>	<u>\$ 57,913,914</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 6,916,587	\$ 5,668,357
Deferred revenue from Schering AG	5,545,919	5,545,920
Current portion of lease obligations	28,101	27,410
Total current liabilities	<u>12,490,607</u>	<u>11,241,687</u>
Deferred revenue from Schering AG, less current portion	9,700,133	11,086,612
Lease obligations, less current portion	7,473	14,763
Other liabilities	<u>291,052</u>	<u>307,060</u>
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; 30,649,314 and 30,565,746 shares issued and outstanding at March 31, 2006 and December 31, 2005, respectively	124,144,276	123,443,666
Accumulated deficit	(93,497,639)	(88,187,373)
Accumulated other comprehensive income	9,916	7,499
Total stockholders' equity	<u>30,656,553</u>	<u>35,263,792</u>
Total liabilities and stockholders' equity	<u>\$ 53,145,818</u>	<u>\$ 57,913,914</u>

See accompanying notes.

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

	<u>Three Months Ended March 31,</u>	
	<u>2006</u>	<u>2005</u>
<b>Revenue:</b>		
Collaboration revenue from Schering AG	\$ 4,053,618	\$ —
<b>Operating expenses:</b>		
Research and development	8,110,502	3,123,424
General and administrative	1,768,322	1,742,946
Total operating expenses	<u>9,878,824</u>	<u>4,866,370</u>
Operating loss	(5,825,206)	(4,866,370)
<b>Other income (expense):</b>		
Other income	—	4,160
Interest income	515,940	89,500
Interest expense	(1,000)	(2,625)
Total other income, net	<u>514,940</u>	<u>91,035</u>
Net loss	<u>\$ (5,310,266)</u>	<u>\$ (4,775,335)</u>
Basic and diluted net loss per share	\$ (0.17)	\$ (0.22)
Shares used in computation of basic and diluted net loss per share	30,620,878	21,353,868

See accompanying notes.

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

	<b>Three Months Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>
<b>Operating activities:</b>		
Net loss	\$ (5,310,266)	\$ (4,775,335)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	135,653	181,733
Non-cash stock-based compensation	384,603	3,170
Amortization (accretion) related to cash equivalent/marketable securities	2,417	(80)
Gain on sale of capital equipment	—	(4,160)
Changes in operating assets and liabilities:		
Accounts receivable from Schering AG	3,583,110	—
Other current assets	8,786	174,812
Other long term assets	7,836	—
Accounts payable and accrued expenses	1,248,230	(940,226)
Deferred revenue from Schering AG	(1,386,480)	—
Other liabilities	(16,008)	(16,008)
Net cash used in operating activities	(1,342,119)	(5,376,094)
<b>Investing activities:</b>		
Purchases of capital equipment	(58,789)	(67,869)
Proceeds from sale of capital equipment	—	4,160
Proceeds from sales of marketable securities	—	2,695,968
Proceeds from maturities of marketable securities	—	6,202,000
Net cash (used in) provided by investing activities	(58,789)	8,834,259
<b>Financing activities:</b>		
Proceeds from exercise of common stock warrants	287,220	—
Proceeds from issuance of common stock under employee benefit plans	28,787	31,527
Payments on lease obligations	(6,599)	(40,151)
Net cash provided by (used in) investing activities	309,408	(8,624)
Change in cash and cash equivalents for the period	(1,091,500)	3,449,541
Cash and cash equivalents at beginning of period	49,317,845	416,847
Total cash and cash equivalents	\$ 48,226,345	\$ 3,866,388
<b>Supplemental cash flow information:</b>		
Interest paid	\$ 1,000	\$ 2,625

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, 2005 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, 2005 and filed with the Securities and Exchange Commission on March 16, 2006. Certain prior year amounts have been reclassified to conform to the 2006 presentation.

**2. Collaboration and License Agreement with Schering AG**

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 paid Sonus an upfront license fee of \$20 million and pays Sonus for research and development services performed equal to 50% of eligible Product research and development costs. In addition, Schering may pay Sonus (i) product milestone payments of up to \$132 million upon the achievement of certain U.S., European Union and Japanese clinical and regulatory milestones, (ii) sales milestone payments of up to \$35 million upon the achievement of certain annual worldwide net sales, and (iii) 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 and trials to support launch of the Product and planned trials for additional indications. 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.

During the three month period ended March 31, 2006, the Company recognized revenue of \$1.4 million as amortization of the upfront license fee and an additional \$2.7 million related to research and development services performed for the Phase 3 trial for TOCOSOL Paclitaxel and related drug supply and manufacturing costs. The Company expects to recognize revenue related to amortization of the upfront fee and cost reimbursements through the end of the development period which is currently estimated as the

end of 2008. As the clinical development program for TOCOSOL Paclitaxel is still being finalized in collaboration with Schering AG, we cannot estimate the total costs or expected reimbursements at this time. The Company reduced the revenue to be recognized over the development period related to the \$20 million upfront license payment by \$2.3 million. This represented the excess fair value of the warrants purchased

by the Investors above the amount paid in connection with their equity investment in Sonus. This adjustment was made because both the equity investment and the upfront payment were considered to be a single unit of accounting. As of March 31, 2006, the Company had \$15.2 million in deferred revenue related to the unamortized upfront payment (net of the adjustment for the warrant valuation) as well as \$3.6 million in current and long-term receivables from Schering AG on its balance sheet.

### 3. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	March 31, 2006	December 31, 2005
Accounts payable	\$ 367,620	\$ 1,260,513
Accrued expenses:		
Clinical trials	4,360,752	2,224,447
Product manufacturing	1,406,347	438,332
Compensation	538,495	1,455,329
Other	243,373	289,736
	<u>\$ 6,916,587</u>	<u>\$ 5,668,357</u>

### 4. Comprehensive Income (Loss)

	Three months ended March 31,	
	2006	2005
Net loss	\$ (5,310,266)	\$ (4,775,335)
Unrealized gain on marketable securities	2,417	7,210
Comprehensive loss	<u>\$ (5,307,849)</u>	<u>\$ (4,768,125)</u>

### 5. Stockholders' Equity

#### Common Stock Issuances

During the first quarter of 2006, the Company recorded \$287,000 in proceeds from the issuance of 70,000 shares of common stock from the exercise of common stock warrants, in addition to \$29,000 in proceeds from the issuance of 13,000 shares of common stock from the issuance of shares under employee benefit programs.

#### Employee Stock Plans

The Company has stock option plans whereby shares of common stock are reserved for future issuance pursuant to stock option grants or other issuances. Under the 2000 Stock Incentive Plan, an incremental number of shares equal to four percent of the Company's common stock outstanding as of December 31 of each year commencing December 31, 2000 are made available for issuance under the plan up to a lifetime maximum of five million shares. Employee stock options vest over a period of time determined by the Board of Directors, generally four years, and director stock options are generally fully vested on the date of grant. Stock options generally are granted at the fair market value on the date of grant and expire ten years from the date of grant.

The Company has an employee stock purchase plan whereby employees may contribute up to 15% of their compensation to purchase shares of the Company's common stock at 85% of the stock's fair market value at the lower of the beginning or end of each six-month offering period. At March 31, 2006, a total of 100,000 shares remain available for purchase by employees under the plan.

#### Adoption of SFAS 123R

The Company adopted the requirements of SFAS No. 123 (revised 2004), "Share-Based Payment," (or "SFAS 123R") January 1, 2006, utilizing the "modified prospective" method. The Company uses the Black-Scholes-Merton option-pricing model as the most appropriate fair-value method for its awards and recognizes compensation cost on a straight-line basis over its awards' vesting periods in accordance with the provisions of SFAS 123R. In valuing its options using the Black-Scholes-Merton option-pricing model, the Company makes assumptions about risk-free interest rates, dividend yields, volatility and weighted average expected lives, including estimated forfeiture rates, of the options. Risk-free interest rates are derived from United States treasury securities as of the option grant date. Dividend yields are based on the Company's historical dividend payments, which have been zero to date. Volatility is derived from the historical volatility of the Company's common stock as traded on NASDAQ. Forfeiture rates are estimated using historical actual forfeiture rates that resulted over the estimated life of the option grant for options granted as of the beginning of the forfeiture measurement period. These rates are adjusted on a quarterly basis and any change in compensation expense is recognized in the period of the change. The weighted average expected lives of the options is based on historical experience of option exercises and the average vesting option schedule.

For unvested awards granted prior to the adoption date, compensation expense is based on the original grant date fair value measurement under SFAS 123, "Accounting for Stock-Based Compensation". We currently believe that the assumptions used to generate those fair values are appropriate and therefore have not revised those calculations.

#### Prior to the adoption of SFAS 123R

The Company previously applied Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations and provided the required pro forma disclosures of SFAS No. 123.

The pro-forma information for the three months ended March 31, 2005 was as follows:

	March 31, 2005
Net loss, as reported	\$ (4,775,335)
Add: Stock-based employee compensation expense included in reported net loss	3,170

Deduct: Stock-based employee compensation expense determined under the fair value based method		(397,272)
Pro forma net loss	\$	<u>(5,169,437)</u>
Earnings per share:		
Basic and diluted-as reported	\$	(0.22)
Basic and diluted-pro forma	\$	<u>(0.24)</u>

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### Impact of the adoption of SFAS 123R

The Company elected to implement SFAS 123R using the modified prospective application method. Accordingly, during the three months ended March 31, 2006, the Company recorded stock-based compensation cost totaling the amount that would have been recognized had the fair value method been applied since the effective date of SFAS 123 for unvested options outstanding as of January 1, 2006 and recorded compensation expense under the provisions of SFAS 123R for options granted during the three month period ended March 31, 2006. Previously reported amounts have not been restated. As the Company uses a full valuation allowance with respect to deferred taxes, the adoption of SFAS 123R had no impact on deferred taxes or cash flow. The effect of recording stock-based compensation for the three month period ended March 31, 2006 was as follows:

		<u>March 31, 2006</u>
Stock-based compensation expense:		
General & administrative	\$	(186,135)
Research & development		<u>(198,468)</u>
Total stock-based compensation expense		(384,603)
Tax effect on stock-based compensation		—
Net effect on income	\$	<u>(384,603)</u>
Effect on earnings per share:		
Basic and diluted	\$	<u>(0.013)</u>

As of January 1, 2006, the Company had an unrecorded deferred stock-based compensation balance related to stock options of \$5.4 million before estimated forfeitures. In the Company's pro forma disclosures prior to the adoption of SFAS 123R, the Company accounted for forfeitures upon occurrence. SFAS 123R requires forfeitures to be estimated at the time of grant and revised if necessary in subsequent periods if actual forfeitures differ from those estimates. Accordingly, as of January 1, 2006, the Company estimated that the stock-based compensation for the awards not expected to vest was \$1.2 million, and therefore, the proforma deferred stock-based compensation balance related to stock options was adjusted to \$4.2 million after estimated forfeitures.

As of March 31, 2006, the proforma deferred stock-based compensation balance related to stock options after adjusting for estimated forfeitures was \$3.9 million and will be recognized over an estimated weighted average period of 2.2 years.

The fair value of each stock option used in the calculations under SFAS 123R is estimated using the Black-Scholes-Merton 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 77.6% and 88.5% as of March 31, 2006 and 2005, respectively, (6) forfeiture rate of 14.83% as of March 31, 2006, and (7) a risk-free interest rate of 4.55% and 3.88% as of March 31, 2006 and 2005, respectively.

The Black-Scholes-Merton option-pricing model was developed for use in estimating the fair value of short-lived exchange traded options that have no vesting restrictions and are fully transferable. In addition, option-pricing models require the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The Company will evaluate its assumptions on a regular basis. These evaluations may result in changes to assumptions which may have a material effect on compensation expense recorded under SFAS 123R. There were no such changes as of March 31, 2006.

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### Stock Option Activity

The following is a summary of option activity for the first quarter of 2006:

	Shares Available for Grant	Options Outstanding	
		Number of Shares	Weighted-Average Exercise Price
December 31, 2005	1,652,431	3,819,170	\$ 4.66
Grants	(35,000)	35,000	5.69
Exercises	—	(10,000)	0.88
Cancellations	10,000	(14,500)	4.98
March 31, 2006	<u>1,627,431</u>	<u>3,829,670</u>	<u>\$ 4.68</u>

The intrinsic value of options exercised during the first quarters of 2006 and 2005 was \$55,000 and \$7,000, respectively. The estimated fair value of shares vested during the first quarters of 2006 and 2005 was \$408,264 and \$454,610, respectively. The weighted-average estimated fair value of stock options granted during the three months ended March 31, 2006 and 2005 was \$3.42 and \$2.78, respectively, based on the assumptions in the Black-Scholes valuation model discussed above.

Range of Exercise Prices	Options Outstanding			Options Exercisable		
	Number of Shares Outstanding	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price	Number of Shares Outstanding	Weighted-Average Remaining Contractual Life (in years)	Weighted-Average Exercise Price
\$0.63 - \$1.46	227,975	4.68	\$ 0.73	227,666	4.67	\$ 0.73

\$2.03 - \$3.72	1,091,507	7.83	\$	2.85	621,179	7.46	\$	2.73
\$3.79 - \$6.00	1,827,143	8.27	\$	5.10	605,290	6.09	\$	5.25
\$6.25 - \$8.08	655,412	5.02	\$	6.98	566,202	4.58	\$	7.05
\$19.38 - \$20.50	15,000	1.57	\$	19.75	15,000	1.57	\$	19.75
\$37.00 - \$44.00	12,633	1.58	\$	39.77	12,633	1.58	\$	39.77
	<u>3,829,670</u>				<u>2,047,970</u>			

## 6. Subsequent Event

On May 2, 2006, the Company closed on the issuance of approximately 6.1 million shares of common stock in a registered direct offering for gross proceeds of \$30.6 million (approximately \$28.6 million net of transaction costs). The common stock was sold at a price of \$5.00 per share and was previously registered through a shelf registration statement on Form S-3 that was declared effective by the SEC earlier in 2006.

## 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:

- timing and amount of future contractual payments, product revenue and operating expenses;
- progress and preliminary results of clinical trials;
- our anticipated future capital requirements and the terms of any capital financing agreements;
- 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:

- uncertainty of governmental regulatory requirements and lengthy approval process;
- future capital requirements and uncertainty of payments under corporate partnerships or additional funding through either debt or equity financings;
- 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;
- potential for product liability issues and related litigation;
- potential for claims arising from the use of hazardous materials in our business;
- volatility in the value of our common stock,
- continued listing on the NASDAQ National Market; and
- other factors set forth under "Risk Factors" contained in our Annual Report on Form 10K for the fiscal year ended December 31, 2005 filed on March 16, 2006 and in this Quarterly Report on Form 10Q.

### 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 oncology drugs that provide better therapeutic alternatives for cancer patients, including improved efficacy, safety, and tolerability, and are more convenient to use. Our business strategy is as follows:

- Develop proprietary formulations of therapeutic drugs utilizing our proprietary TOCOSOL® technology; and
- Identify and acquire products/technologies that are complementary to our focus in oncology in order to broaden our business and market opportunities.

#### Proprietary TOCOSOL technology

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

#### TOCOSOL Paclitaxel

Our lead oncology product 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 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 of TOCOSOL Paclitaxel, which is currently underway);
- offers the convenience of a ready-to-use formulation that does not require 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 (i.v.) tubing, filters or other apparatus; and
- can be administered in small volumes of 15 to 35 milliliters compared to volumes of several hundred milliliters of i.v. solution that are required for dosing of Taxol, Taxotere, or ABRAXANE®.

We concluded a Phase 1 study of 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<sup>2</sup> to 225 mg/m<sup>2</sup> every three weeks. The maximum tolerated dose (MTD) was estimated in this study to be 200 mg/m<sup>2</sup> every three weeks, slightly higher than the approved dose of Taxol at 175 mg/m<sup>2</sup> every three weeks. TOCOSOL Paclitaxel was generally well tolerated in all patients treated. All patients in the Phase 1 study had advanced cancers that were no longer responding to previous therapies or for which no standard therapy existed. Five patients with different types of cancers had objective partial responses during the course of the study, including four patients who had previously been treated with taxane-containing chemotherapy regimens (under RECIST, partial response is defined as reduction in the sum of the longest tumor dimensions of target lesions of ≥30% 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 a 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/m<sup>2</sup> per week in the ovarian and lung cancer trials, and 100 mg/m<sup>2</sup> per week in the bladder cancer trial, based on observations among a small number of patients treated for a few weeks. Subsequent review of actual doses administered across all patients in all studies over extended treatment periods indicated that patients assigned to receive weekly doses of 100 mg/m<sup>2</sup> or 120 mg/m<sup>2</sup> 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, including objective response rate, time to disease progression, and overall survival duration. Data review, confirmation and analysis are now complete, and databases have 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 underwent CT scans to confirm anti-tumor responses according to RECIST. Final analyses of all data are expected to be complete by mid-2006.

In the ovarian cancer study, 51 enrolled patients were evaluable for anti-tumor effect. Twenty of the 51 evaluable patients (39%; 95% Confidence Interval 26% - 54%) 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).

In the non-small cell lung cancer study, 42 enrolled patients were evaluable for anti-tumor effect. Nine of the 42 evaluable patients (21%; 95% Confidence Interval 10% - 37%) were reported as having objective responses, including three complete responses and six partial responses; 18 additional patients were reported to have stable disease.

In the bladder cancer study, 27 patients enrolled were evaluable for anti-tumor effect. Nine of the 27 evaluable patients (33%; 95% Confidence Interval 17% - 54%) were reported as having objective responses, including two complete responses and seven partial responses; 11 additional patients were reported to have stable disease.

The response rates for these three Phase 2a 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 in the Phase 2a studies, clinical 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 December 2005:

Cancer Type	Median Survival (wks)	95% CI (wks)
Ovarian	64.1	(49.1 - 106.4)
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 of 53%, (95% Confidence Interval 38% - 68%). Review of all radiographic images by an independent radiologist who had no information about individual patients' treatment or non-radiographic response assessments reported a confirmed objective response rate of 49%, (95% Confidence Interval 34% - 64%). Three patients remain on active treatment at the end of March 2006. We currently estimate the median time to disease progression at 7.2 months (95% Confidence Interval 5.5 - 9.8 months) and patient follow-up for survival duration will continue throughout the next two years.

In addition to being assessed for anti-tumor efficacy, patients are also monitored for adverse events in all clinical studies. The most significant adverse events expected with taxanes are neutropenia and peripheral neuropathy. Among 210 patients treated in the Phase 2 clinical trials as of April 2006, the incidence of at least one episode of Grade 4 neutropenia (absolute neutrophil count <500 cells/mm<sup>3</sup>) during treatment was 19%. 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 9% of patients cumulatively, 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 with the approved dosing regimen of 175 mg/m<sup>2</sup> 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-related toxicities, sometimes called "hypersensitivity reactions" and involving pain, flushing, shortness of breath or chest tightness, were infrequently observed following more than 3,500 administered doses. Investigators have reported that infusion-related toxicities associated with our product could be ameliorated by temporary (a few minutes) interruption of infusion, while corticosteroid premedications were not helpful. Infusion-related toxicities 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 2 clinical trials may or may not be indicative of the final results upon completion of the ongoing studies or our Phase 3 pivotal 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, nor from submitting our intended New Drug Application (NDA) based on the results of that trial.

Our objective is to work with our corporate partner (Schering AG) to advance final clinical development, gain marketing approval and maximize the commercial opportunity for TOCOSOL Paclitaxel. Our regulatory strategy is to gain the fastest possible market entry with a competitive label, while pursuing opportunities 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 exposure in the circulation over time after single doses of TOCOSOL Paclitaxel and Taxol, with both drugs given at 175 mg/m<sup>2</sup> 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. After meetings with the FDA, and based on preclinical and clinical data generated to date, the FDA indicated that it was appropriate for Sonus to conduct a single Phase 3 clinical trial that would be the basis for submission of a NDA for TOCOSOL Paclitaxel under the 505(b)(2) regulatory mechanism. The FDA and Sonus finalized the study design and plans for conducting and analyzing the results of the Phase 3 trial under a Special Protocol Assessment ("SPA"), which was completed in June 2005. The Phase 3 study is comparing the safety and efficacy of TOCOSOL Paclitaxel administered weekly with Taxol administered weekly.

Based on agreement from the FDA to use the results of a single Phase 3 trial with a primary endpoint of objective response rate, we believe that the NDA for TOCOSOL Paclitaxel could be submitted within 12 months after the completion of patient enrollment into the Phase 3 study, which we believe may occur by the end of September 2006. We anticipate that submission of our NDA is likely to occur by the end of 2007. The FDA has indicated to Sonus that NDA approval under 505(b)(2) will require either (i) demonstration of superior efficacy of TOCOSOL Paclitaxel as compared to Taxol; or (ii) demonstration of non-inferior efficacy of TOCOSOL Paclitaxel as compared to Taxol, and either a change of the approved label for Taxol and generic equivalents to include a weekly dosing schedule or availability of reviewable data from a Phase 3 trial comparing the efficacy of Taxol using a weekly dosing schedule to that of 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 adversely affected by these requirements. The clinical trial Protocol and Statistical Analysis Plan approved under the SPA provide for sequential superiority analyses for efficacy of TOCOSOL Paclitaxel compared to Taxol, provided that we first demonstrate a non-inferior objective response rate; however, there can be no assurance that the Phase 3 clinical trial data will demonstrate that TOCOSOL Paclitaxel has efficacy that 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 have been

conducted by third parties, utilizing Taxol on a weekly versus a three-weekly basis, and data from those studies may be available for submission to the FDA in support of our NDA. 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 given weekly versus three-weekly, substantial additional costs and time would be required before the NDA submission for



- *New indications for taxanes.* In conjunction with our corporate partner, Schering AG, we may pursue clinical development of TOCOSOL Paclitaxel for the treatment of other types of cancer, including indications for which Taxol has been approved as well as for diseases for which Taxol is used but not approved, such as treatment of inoperable or metastatic urothelial transitional cell cancers (mostly urinary bladder cancers). 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, and in Spain and the U.K. during 2005, 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; however, we now expect to complete enrollment in this study in 2006. In December 2004, the FDA granted an Orphan Drug designation to TOCOSOL Paclitaxel for the treatment of non-superficial urothelial cancer.

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 submissions 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. Our current estimate for the total cost of the Phase 3 trial is between \$45 million and \$50 million. Under our Collaboration and License Agreement with Schering AG, dated October 17, 2005, Schering will fund 50% of these costs. In addition, it is anticipated that we will collaborate with Schering on additional studies of TOCOSOL Paclitaxel. Under the terms of the agreement with Schering AG, we are also obligated to fund 50% of the costs of certain studies conducted by Schering AG in support of commercialization activities for the U.S. market. The exact cost and timing of these studies is yet to be finalized. The currently ongoing Phase 3 trial will constitute the bulk of the Company's clinical trial spending in the near term, and at least half of the cost of the Phase 3 trial will occur in the first 12 months after the start of the study (September 2005 through September 2006). 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 product approval.

#### 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 technology. Our second oncology drug candidate, SN2310 Injectable Emulsion, is a novel camptothecin derivative discovered and formulated with Sonus' proprietary TOCOSOL technology. Camptothecins are among the most important classes of anti-cancer drugs introduced in recent years; however, the marketed camptothecin analogs pose substantial challenges in terms of efficacy, tolerability and difficulty of use. Our objective with SN2310 Injectable Emulsion is to provide a product that has enhanced tolerability and anti-tumor activity compared with the approved products. We anticipate submitting an Investigational New Drug Application (IND) to the

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U. S. Food and Drug Administration for SN2310 Injectable Emulsion and initiating its clinical testing in 2006. There are currently two marketed hydrophilic (water-based) camptothecin analogs that are based on chemical modifications to the native 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 SN2310 Injectable Emulsion are preliminary, and we cannot give any assurance that this compound will be successful or that it will progress to clinical trials. Advancing this development candidate 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 acquisitions of other 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 March 31, 2006, eight United States patents and four patents outside the U.S., one each in Canada, Taiwan, Mexico and India have been issued pertaining to our proprietary TOCOSOL technology. 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.

#### **Collaboration and License Agreement with Schering AG**

On October 17, 2005, we entered into a Collaboration and License Agreement with Schering AG, a German corporation, pursuant to which, among other things, we granted Schering an exclusive, worldwide license to TOCOSOL Paclitaxel. Schering paid us an upfront license fee of \$20 million and pays us for research and development services performed equal to 50% of eligible research and development costs related to TOCOSOL Paclitaxel. In addition, Schering may pay us (i) product milestone payments of up to \$132 million upon the achievement of certain U.S., European Union and Japanese clinical and regulatory milestones, (ii) sales milestone payments of up to \$35 million upon the achievement of certain annual worldwide net sales, and (iii) 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 U.S. development program consisting of the ongoing initial pivotal trial for FDA NDA approval in metastatic breast cancer and trials to support launch of TOCOSOL Paclitaxel and planned trials for additional indications. We have 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.

On April 13, 2006, a wholly owned subsidiary of Bayer AG, a German corporation, or Bayer, submitted a formal tender offer to the stockholders of Schering to purchase all of the outstanding shares of Schering. We are not aware of any effects Bayer's proposed acquisition of Schering would have on our business, and we are uncertain if the proposed acquisition will have any effect on our business, financial condition or results of operations in the future.

On March 2, 2006, in accordance with the Collaboration and License Agreement with Schering AG, Schering AG exercised their right to assume responsibility for all manufacturing of TOCOSOL Paclitaxel.

#### **Results of Operations**

As of March 31, 2006, our accumulated deficit was approximately \$93.5 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 and payments received under corporate partnership agreements. 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.

Our revenue was \$4.1 million for the three months ended March 31, 2006 as compared with \$0 for the same period in 2005. Revenue in the first quarter of 2006 was fully attributable to the collaboration agreement with Schering AG. We recognized \$1.4 million in amortization of an upfront license fee received from Schering AG and an additional \$2.7 million in research and development funding related to the Phase 3 trial for TOCOSOL Paclitaxel. Amortization of the \$20 million upfront fee, net of a \$2.3 million adjustment related to the excess fair value of warrants issued to Schering AG in connection with the license arrangement, will continue until the end of the development period for TOCOSOL Paclitaxel, which is currently estimated to conclude at the end of 2008. The estimated development period represents the currently estimated date for FDA approval assuming no further research is required and the results of the Phase 3 trial successfully meet its endpoints. This estimate is subject to change as facts and circumstances surrounding our Phase 3 trial for TOCOSOL Paclitaxel change. The

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license arrangement also includes reimbursement of 50% of research and development costs during this time. We expect revenue during the remainder of 2006 to increase due to continued amortization of the upfront license fee, and as the level of research and development funding increases.

Our research and development (R&D) expenses were \$8.1 million for the three months ended March 31, 2006 compared with \$3.1 million for the same period in 2005. The increase was primarily the result of the spending associated with the Phase 3 clinical trial for TOCOSOL Paclitaxel including both clinical and drug supply and manufacturing costs. We expect R&D expenses during the remainder of 2006 to increase as we continue to advance our Phase 3 and other related clinical trial development related to TOCOSOL Paclitaxel.

Our general and administrative (G&A) expenses were \$1.8 million for the three months ended March 31, 2006 compared with \$1.7 million for the same period in 2005. We expect G&A expenses during 2006 to remain generally in line with levels experienced during the first three months of 2006.

We expect our total operating expenses during the remainder of 2006 to increase substantially as we continue to advance our Phase 3 and other related clinical trial development related to TOCOSOL Paclitaxel. We estimate that R&D spending will comprise approximately 80%-90% of the anticipated spending in 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 interest income, net of interest expense, was \$515,000 for the three months ended March 31, 2006 compared with \$87,000 for the same period in 2005. The increase was due primarily to higher levels of invested cash in the first three months of 2006 in addition to generally higher interest rates than the same period in 2005.

The Company had no income tax expense for the three months ended March 31, 2006 or 2005 as it had incurred significant losses and has significant net operating loss carryforwards.

#### **Liquidity and Capital Resources**

We have historically financed operations with proceeds from equity financings and payments under corporate partnerships with third parties. At March 31, 2006, we had cash and cash equivalents totaling \$48.2 million compared to \$49.3 million at December 31, 2005. The decrease was primarily due to the net loss for the first quarter 2006 of \$5.3 million, payment of 2005 incentive bonuses in 2006 of \$1.2 million and other timing differences. These decreases were offset in part by \$6.3 million in payments received from Schering AG under the collaboration agreement.

On May 2, 2006, we closed on a registered direct offering that raised gross proceeds of approximately \$30.6 million (\$28.6 million in net proceeds) through the issuance of approximately 6.1 million shares of our common stock. Including the net proceeds from this sale of common stock, our proforma cash and cash equivalents as of March 31, 2006 would have been \$76.8 million.

Net cash used in operating activities for the three months ended March 31, 2006, and 2005, was \$1.3 million and \$5.4 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. The decrease in net cash used in operating activities from the three months ended March 31, 2005 to the three months ended March 31, 2006 was primarily due to payments received from Schering AG, partially offset by increased R&D expenditures.

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Net cash (used in) provided by investing activities for the three months ended March 31, 2006, and 2005 was (\$59,000) and \$8.8 million, respectively. The net cash used in investing activities during the three month period ended March 31, 2006 was due to purchases of property and equipment. The net cash provided by investing activities during the same period in the prior year was primarily due to sales and maturities of marketable securities occurring in the normal course of business. Activity related to short-term marketable securities relates 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. All of the Company's investments were in cash equivalent securities during the three month period ended March 31, 2006.

Net cash provided by (used in) financing activities for the three months ended March 31, 2006, and 2005 was \$309,000 and (\$9,000), respectively. The net cash provided by financing activities during the three month period ended March 31, 2006 was primarily due to proceeds from the exercise of common stock warrants. The net cash used in financing activities during the same period in the prior year was primarily related to payments on lease obligations, offset in part by the issuance of common stock under employee benefit plans.

We expect that our cash requirements will continue to increase in future periods due to the development and commercialization costs associated with TOCOSOL Paclitaxel and other product candidates. We believe that existing cash and cash equivalents, in addition to payments under our agreement with Schering AG and the \$28.6 million in net proceeds raised in the May 2006 registered direct offering, will be sufficient to fund operations into 2008. 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 for the U.S. The exact cost and timing of these studies is yet to be finalized. In addition, 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. Our current estimate for the total cost of the Phase 3 clinical trial is between \$45 and \$50 million. We may need additional capital in 2008 to support the continued development and commercialization of TOCOSOL Paclitaxel, our obligations under the Collaboration and License Agreement with Schering AG, the development of other product candidates 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, which we believe will occur before the end of September 2006. 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 AG;

- 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 \$971,000 and \$38,000 under our leasehold financing agreements. Under the Collaboration and License Agreement with Schering AG, we are obligated to fund 50% of the costs of certain studies conducted by Schering AG. As these additional studies have not yet been finalized, no dollar amounts have been

disclosed below. The following table summarizes our contractual obligations under these agreements, including interest as of March 31, 2006:

Contractual Obligations	Total	Less than			More than 5 years
		1 year	1-3 years	3-5 years	
Lease financing obligations	\$ 37,991	\$ 30,393	\$ 7,598	\$ —	\$ —
Operating lease obligations	970,544	719,052	251,492	—	—
Total	\$ 1,008,535	\$ 749,445	\$ 259,090	\$ —	\$ —

### Critical Accounting Policies and Estimates

We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America. As such, we are required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the periods presented. Actual results could differ significantly from those estimates under different assumptions and conditions. We believe that the following discussion addresses our most critical accounting estimates which are those that are most important to the portrayal of our financial condition and results of operations and which require our most difficult and subjective judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. We also have other policies that we consider key accounting policies; however, these policies do not meet the definition of critical accounting estimates, because they do not generally require us to make estimates or judgments which are difficult or subjective.

- *Cash and Cash Equivalents.* We consider investments in highly liquid instruments purchased with a remaining maturity at purchase 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 twelve months long-term and maturity less than twelve 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. These arrangements may include upfront non-refundable payments, development milestone payments, payments for research and development services performed and product sales royalties or revenue. Our revenue recognition policies are based on the requirements of SEC Staff Accounting Bulletin No. 104 "Revenue Recognition," and, for contracts with multiple deliverables, we allocate arrangement consideration based on the fair value of the elements under guidance from Emerging Issues Task Force Issue 00-21 ("EITF 00-21"), "Revenue Arrangements with Multiple Deliverables." Under EITF 00-21, revenue arrangements with multiple deliverables are divided into separate units of accounting and revenue is allocated to these units based upon relative fair values with revenue recognition criteria considered separately for each unit.

Nonrefundable upfront technology license fees, for product candidates where we are providing continuing services related to product development, are deferred and recognized as revenue over the development period.

Milestones, in the form of additional license fees, typically represent nonrefundable payments to be received in conjunction with the achievement of a specific event identified in the contract, such as initiation or completion of specified clinical development activities and / or regulatory approvals. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other performance on our part. We recognize such milestones as revenue when they become due and collection is reasonably assured. When a milestone does not represent the culmination of a distinct earnings process, we recognize revenue in a manner similar to that of an upfront technology license fee.

The timing and amount of revenue that we recognize from licenses of technology, either from upfront fees or milestones where we are providing continuing services related to product development, is primarily dependent upon our estimates of the development period. We define the development period as the point from which research activities commence up to FDA approval of our submission assuming no further research is necessary. As product candidates move through the development process, it is necessary to revise these estimates to consider changes to the product development cycle, such as changes in the clinical development plan, regulatory requirements, or various other factors, many of which may be outside of our control. Should the FDA require additional data or information, we would adjust our development period estimates accordingly. The impact on revenue of changes in our estimates and the timing thereof is recognized prospectively over the remaining estimated product development period. Revenue from research and development services performed under collaboration agreements is generally recognized in the period when the services are performed. Payments received in excess of amounts earned are recorded as deferred revenue.

Royalty revenue is generally recognized at the time of product sale by the licensee.

- *Research and Development Expenses.* Pursuant to SFAS No. 2 "Accounting for Research and Development Costs," our research and development costs are expensed as incurred. 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. Clinical trial expenses, which are included in research and development expenses and represent a significant portion of our research and development expenditures, represent obligations resulting from our contracts with various clinical research organizations in connection with conducting clinical trials for our product candidates. We recognize expenses for these contracted activities based on a variety of factors, including actual and estimated labor hours, clinical site initiation activities, patient enrollment rates, estimates of external costs and other activity-based factors. We believe that this method best approximates the efforts expended on a clinical trial with the expenses we record. We adjust our rate of clinical expense recognition if actual results differ from our estimates.

- *Valuation of Equity Instruments.* We adopted the requirements of SFAS 123R, "Share-Based Payment," effective January 1, 2006, utilizing the "modified prospective" method. We use the Black-Scholes-Merton option-pricing model as the most appropriate fair-value method for our awards and recognize compensation cost on a straight-line basis over our awards' vesting periods in accordance with the provisions of SFAS 123R. In valuing our options using the Black-Scholes-Merton option-pricing model, we make assumptions about risk-free interest rates, dividend yields, volatility and weighted average expected lives of the options. Risk-free interest rates are derived from United States treasury securities as of the option grant date. Dividend yields are based on our historical dividend payments, which have been zero to date. Volatility is derived from the historical volatility of our common stock as traded on NASDAQ. Forfeiture rates are estimated using historical actuals over the estimated life of the option grant. These rates are adjusted on a quarterly basis and any change in compensation expense is

recognized in the period of the change. The weighted average expected lives of the options is based on historical experience of option exercises and the average vesting option schedule. For unvested awards granted prior to the adoption date, compensation expense is based on the original grant date fair value measurement under SFAS 123. We currently believe that the assumptions used to generate those fair values are appropriate and therefore are not revisiting those calculations.

We previously applied Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and related Interpretations and provided the required pro forma disclosures of SFAS No. 123, "Accounting for Stock-Based Compensation".

### **Effects of Recent Accounting Pronouncements**

In December 2004, the FASB issued SFAS No. 123R (revised 2004), "Share-Based Payment." SFAS No. 123R requires us to measure all employee stock-based compensation awards using a fair value method and record such expense in our financial statements. In March 2005, the SEC issued SAB 107, which provides the Staff's views regarding interactions between SFAS No. 123R and certain SEC rules and regulations and provides interpretations of the valuation of share-based payments for public companies. The adoption of SFAS No. 123R requires additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. As the Company uses a full valuation allowance with respect to deferred taxes, the adoption of SFAS No. 123R had no impact on deferred taxes or cash flow. The adoption of SFAS No. 123R on January 1, 2006 had a material impact on our results of operations and financial position, resulting in increased stock-based compensation expense recorded of approximately \$385,000. Of this, \$186,000 related to general and administrative expense and the remaining \$199,000 related to research and development expense. For more information on stock-based compensation costs during the three months ended March 31, 2006, refer to Note 5, "Stockholders' Equity" of the Notes to the Financial Statements included in Item 1 of this quarterly report.

### **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 March 31, 2006, 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, or will be, detected.

Changes in internal control over financial reporting

We have not made any 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 March 31, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Item 1A. Risk Factors**

You should consider the risk 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.

*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 NDA approval under 505(b)(2) will require either (i) demonstration of superior efficacy of TOCOSOL Paclitaxel as compared to Taxol; or (ii) demonstration of non-inferior efficacy of TOCOSOL Paclitaxel as compared to Taxol, and either a change of the approved label for Taxol and generic equivalents to include a weekly dosing schedule or availability of reviewable data from a Phase 3 trial comparing the efficacy of Taxol using a weekly dosing schedule to that of 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 adversely affected by these requirements. The clinical trial Protocol and Statistical Analysis Plan approved under the SPA provide for sequential superiority analyses for efficacy of TOCOSOL Paclitaxel compared to Taxol, provided that we first demonstrate a non-inferior objective response rate; however, there can be no assurance that the Phase 3 clinical trial data will demonstrate that TOCOSOL Paclitaxel has efficacy that 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 have been conducted by third parties, utilizing Taxol on a weekly versus a three-weekly basis, and data from those studies may be available for submission to the FDA in support of our NDA. 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 given 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.

*We may need additional capital in the future to support the continued development and commercialization of TOCOSOL Paclitaxel, our obligations under the Collaboration and License Agreement with Schering AG and to fund continuing operations.*

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 and cash equivalents, in addition to payments pending and cost sharing arrangements under our Collaboration and License Agreement with Schering AG and the \$28.6 million in net proceeds raised in the May 2006 registered direct offering, will be sufficient to fund operations into 2008. We may need additional capital to complete the development and commercialization of TOCOSOL Paclitaxel, fund our obligations under the collaborative license agreement with Schering AG, 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 for the U.S. The exact cost and timing of these studies is yet to be finalized. Our current estimate for the total cost of the Phase 3 trial is between \$45 million and \$50 million. 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, which we believe will occur before the end of September 2006. 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;
- our ability to obtain and timing of capital funding under equity or debt financing agreements;
- 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 AG;
- 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 fail to develop new 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 proprietary TOCOSOL technology. Most of our attention and resources are directed to the development of our proprietary TOCOSOL technology, 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 product candidates under development or any future products will be safe or efficacious. If the product candidates 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 March 31, 2006, our accumulated deficit totaled \$93.5 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 AG unless and until we receive regulatory approvals, which are not likely to occur until 2008 and beyond. 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:

- 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 AG;
- 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 depend on third parties for funding, clinical development, manufacturing and distribution of TOCOSOL Paclitaxel.*

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 AG for TOCOSOL Paclitaxel in October 2005. Under the Collaboration and License Agreement, Schering has a worldwide exclusive license to market and

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promote TOCOSOL Paclitaxel and is responsible for clinical development and regulatory activities outside of the U.S. If these arrangements with Schering or other 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.

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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 injectable suspension). In addition, sanofi-aventis has a taxane product, Taxotere (docetaxel), which is similar to paclitaxel and is marketed for the treatment of breast, non-small cell lung and prostate cancers. There are also a number of generic paclitaxel products, identical to Taxol, currently on the market. 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 we do. 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 March 31, 2006, we held eight United States patents and four patents outside the U.S., one each in Canada, Taiwan, Mexico and India pertaining to our proprietary TOCOSOL technology. 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 AG 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.

*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.

*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 March 31, 2006, we had stockholders' equity of approximately \$30.7 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 Capital Market if we satisfy the listing criteria for the NASDAQ Capital 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." 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.

**Item 6. 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: May 10, 2006

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



**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: May 10, 2006

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

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**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: May 10, 2006

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

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**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 March 31, 2006 (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: May 10, 2006

/s/ Michael A. Martino

Michael A. Martino  
President and Chief Executive Officer

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**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 March 31, 2006 (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: May 10, 2006

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

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