
U.S. SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2002

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 issuer (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

State the number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date.

Class	Outstanding at November 1, 2002
Common Stock, \$.001 par value	13,679,152

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

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Items 1, 2, 3, 4 and 5 are not applicable and therefore have been omitted	
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Part I. Financial Information**Item 1. Financial Statements****Sonus Pharmaceuticals, Inc.
Balance Sheets**

	September 30, 2002	December 31, 2001
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 19,245,684	\$ 15,123,914
Other current assets	294,353	343,057
Total current assets	19,540,037	15,466,971
Property and equipment, net	1,403,689	396,711
Total assets	\$ 20,943,726	\$ 15,863,682
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 2,383,661	\$ 1,198,552
Current portion of lease obligations	134,360	—
Total current liabilities	2,518,021	1,198,552
Lease obligations, less current portion	307,627	—
Commitments and contingencies		
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 authorized; no shares issued or outstanding	—	—
Common stock; \$.001 par value; 30,000,000 shares authorized; 13,679,152 and 11,650,797 shares issued and outstanding at September 30, 2002 and December 31, 2001, respectively	55,990,251	43,302,286
Accumulated deficit	(37,903,875)	(28,676,864)
Accumulated other comprehensive income	31,702	39,708
Total stockholders' equity	18,118,078	14,665,130
Total liabilities and stockholders' equity	\$ 20,943,726	\$ 15,863,682

See accompanying notes.

Sonus Pharmaceuticals, Inc.
Statements of Operations
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Revenues	\$ —	\$ 7,561,822	\$ 25,000	\$ 8,748,538
Operating expenses:				
Research and development	2,587,902	1,310,576	7,101,923	3,803,770
General and administrative	785,714	1,177,128	2,512,002	2,489,668
Total operating expenses	3,373,616	2,487,704	9,613,925	6,293,438
Operating income (loss)	(3,373,616)	5,074,118	(9,588,925)	2,455,100
Interest income (expense):				
Interest income	115,021	180,138	380,935	432,219
Interest expense	(11,142)	—	(19,021)	(13,858)
Total interest income, net	103,879	180,138	361,914	418,361
Income (loss) before taxes	(3,269,737)	5,254,256	(9,227,011)	2,873,461
Taxes	—	100,000	—	200,000
Net income (loss)	\$ (3,269,737)	\$ 5,154,256	\$ (9,227,011)	\$ 2,673,461
Basic net income (loss) per share	\$ (0.24)	\$ 0.47	\$ (0.68)	\$ 0.27
Diluted net income (loss) per share	\$ (0.24)	\$ 0.45	\$ (0.68)	\$ 0.26
Shares used in computation of basic net income (loss) per share	13,662,343	10,996,030	13,525,243	9,902,056
Shares used in computation of diluted net income (loss) per share	13,662,343	11,485,397	13,525,243	10,334,488

See accompanying notes.

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

	Nine Months Ended September 30,	
	2002	2001
Operating activities:		
Net income (loss)	\$ (9,227,011)	\$ 2,673,461
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation	261,790	226,927
Amortization of net premium (discount) on marketable securities	206,530	(37,739)
Noncash stock compensation expense	—	50,214
Changes in operating assets and liabilities:		
Other current assets	48,704	(22,294)
Accounts payable and accrued expenses	1,185,109	250,858
Net cash provided by (used in) operating activities	(7,524,878)	3,141,427
Investing activities:		
Purchases of capital equipment and leasehold improvements	(1,268,768)	(106,006)
Purchases of marketable securities	(25,517,473)	(17,364,743)
Proceeds from sales of marketable securities	5,228,717	2,847,792
Proceeds from maturities of marketable securities	15,922,000	8,406,239
Net cash used in investing activities	(5,635,524)	(6,216,718)
Financing activities:		
Proceeds from lease obligations	491,355	—
Payments on lease obligations	(49,368)	—
Proceeds from bank line of credit	—	5,000,000
Repayment of bank line of credit	—	(10,000,000)
Proceeds from collection of stockholder receivable	—	350,000
Proceeds from issuance of common stock	12,687,965	4,499,057
Net cash provided by (used in) investing activities	13,129,952	(150,943)
Change in cash and cash equivalents for the period	(30,450)	(3,226,234)
Cash and cash equivalents at beginning of period	455,073	6,696,610
Cash and cash equivalents at end of period	424,623	3,470,376
Marketable securities at end of period	18,821,061	12,958,649
Total cash, cash equivalents and marketable securities	\$ 19,245,684	\$ 16,429,025
Supplemental cash flow information:		
Interest paid	\$ 19,021	\$ 18,958
Income taxes paid	\$ —	\$ 200,000

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 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 Form 10-K for the year ended December 31, 2001 and filed with the Securities and Exchange Commission on March 5, 2002.

2. Comprehensive Income (Loss)

	Three months ended September 30,		Nine months ended September 30,	
	2002	2001	2002	2001
Net income (loss)	\$(3,269,737)	\$5,154,256	\$(9,227,011)	\$2,673,461
Unrealized gain (loss) on marketable securities	15,502	36,166	(8,006)	46,388
Comprehensive income (loss)	\$(3,254,235)	\$5,190,422	\$(9,235,017)	\$2,719,849

3. Common Stock

In January 2002, the Company sold 1.9 million shares of common stock in a private placement transaction for gross proceeds of \$13.6 million (\$12.5 million net of transaction costs). In connection with the placement, the Company issued warrants to purchase up to 385,800 shares of common stock. The warrants are exercisable at \$9.40 per share and expire in January 2007.

4. Cash, Cash Equivalents and Marketable Securities

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

	September 30, 2002	December 31, 2001
Cash and cash equivalents	\$ 424,623	\$ 455,073
Marketable securities	18,821,061	14,668,841
	\$19,245,684	\$15,123,914

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

This report contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and we intend that such forward-looking statements be subject to the safe harbors created thereby. Examples of these forward-looking statements include, but are not limited to:

- Progress and results of clinical trials;
- Anticipated Investigational New Drug filings and future clinical trials;
- Market acceptance of our products and the potential size of these markets;
- Our anticipated future capital requirements and the terms of any capital financing;
- Timing and amount of future contractual payments, product revenues and operating expenses; and
- Anticipated outcome or financial impact of potential legal matters.

While these forward-looking statements made by us are based on our current beliefs and judgement, they are subject to risks and uncertainties that could cause actual results to vary from the projections in the forward-looking statements. You should consider the risks below carefully in addition to other information contained in this report and in our Annual Report on Form 10-K for the year ended December 31, 2001 before purchasing shares of our common stock. If any of these risks occur, they could seriously harm our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

The discussion and analysis set forth in this document contains trend analysis, discussions of regulatory status and other forward-looking statements. Actual results could differ materially from those projected in the forward-looking statement as a result of the following factors, among others:

- Dependence on the development and commercialization of products;
- History of operating losses and uncertainty of future financial results;
- Uncertainty of governmental regulatory requirements and lengthy approval process;
- Dependence on third parties for funding, clinical development, manufacturing and distribution;
- Future capital requirements and uncertainty of additional funding;
- Uncertainty of U.S. or international legislative or administrative actions;
- Continued listing on the Nasdaq National Market;
- Competition and risk of technological obsolescence;
- Limited manufacturing experience and dependence on a limited number of contract manufacturers and suppliers;
- Ability to obtain and defend patents and protect trade secrets;
- Limitations on third-party reimbursement for medical and pharmaceutical products;
- Dependence on key employees; and
- Volatility in the value of our common stock.

See "Certain Factors That May Affect Our Business and Future Results" on page 12.

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MD&A Overview

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

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

Business Overview

Sonus Pharmaceuticals is applying its expertise in drug delivery to make therapeutic drugs safer, easier to administer and more effective. Our TOCOSOL™ drug delivery technology, a vitamin E based oil-in-water emulsion, may be broadly applicable to multiple drugs, diseases and dosage forms. We currently have a cancer therapy product, TOCOSOL Paclitaxel (formerly known as S-8184), in Phase 2 clinical trials, and we are also developing and or have a number of other potential product candidates in therapeutic areas that target cancer and other serious diseases.

Our first application of TOCOSOL is an injectable paclitaxel emulsion formulation, TOCOSOL Paclitaxel. Paclitaxel is the active ingredient in the world's leading cancer drug, Taxol® (the Bristol-Myers Squibb product), which is approved in the U.S. for the treatment of breast, ovarian and non-small cell lung tumors. We have completed a Phase 1 study for TOCOSOL Paclitaxel and the product is currently under study in four Phase 2 clinical trials to evaluate safety and efficacy in non-small cell lung, ovarian, bladder and colorectal cancers. In addition, on October 1, 2002, we announced the issuance of a United States patent covering TOCOSOL Paclitaxel and our TOCOSOL drug delivery technology platform.

We completed a Phase 1 study for TOCOSOL Paclitaxel in early 2002 after enrolling a total of 37 patients. The objectives of the Phase 1 study were to determine the maximum tolerated dose of TOCOSOL Paclitaxel and to evaluate safety. Preliminary Phase 1 results suggest that TOCOSOL Paclitaxel may provide safety and convenience advantages for both patients and physicians including a reduction in side effects and administration time using a single, quick injection delivered in less than 15 minutes compared to the three-hour infusion of existing formulations of paclitaxel. Based on preclinical and clinical studies to date, we also believe there may be potential efficacy benefits with TOCOSOL Paclitaxel that may result from higher concentrations of the drug delivered to tumors and higher sustained dose density within tumors.

In the Phase 1 study, disease control (defined as partial responses, minor responses and stable disease) was demonstrated in 15 out of 36 evaluable patients. The maximum tolerated dose (MTD) in the Phase 1 study was determined to be 200 mg/m² for administration once every three weeks, which compares to the standard dose of Taxol at 175 mg/m² once every three weeks. Dose limiting toxicities seen in the Phase 1 study include myalgia (muscle aches), fatigue, and neutropenia (low white cell count). No Grade 3 or 4 neuropathy was seen at doses of 200 mg/m² or below. All of the patients in the Phase 1 study had advanced cancers and no other therapeutic options.

We initiated Phase 2 studies for TOCOSOL Paclitaxel in March of 2002. The Phase 2 program is designed to evaluate the safety and efficacy of TOCOSOL Paclitaxel in specific tumor types. Our goal is to obtain a clear measure of efficacy with TOCOSOL Paclitaxel and to quickly determine the indications where the product shows the greatest efficacy. The first four Phase 2 studies are evaluating TOCOSOL Paclitaxel in non-small cell lung, ovarian, bladder and colorectal cancers using weekly dosing of TOCOSOL Paclitaxel. These are single agent, second line studies enrolling patients that have

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not previously had taxane chemotherapy. Each Phase 2 study began with a dose escalation phase to determine the MTD of TOCOSOL Paclitaxel using weekly dose levels of 80, 100 and 120 mg/m².

We have completed the dose escalation stage for the first set of Phase 2 studies during the third quarter and the weekly maximum tolerated dose determined for TOCOSOL Paclitaxel is 120 mg/m² in the non-small cell lung, ovarian and colorectal studies and 100 mg/m² in the bladder study. These continuous weekly doses compare to the typical off-label weekly use of Taxol of 80 to 90 mg/m². In addition, these weekly doses of TOCOSOL Paclitaxel represent cumulative doses of 300 mg/m² to 360 mg/m² over a three-week period, which is nearly twice the approved dose of Taxol given at 175 mg/m² once every three weeks.

When comparing the weekly dosing results of our Phase 2 studies to recently published papers for weekly dosing of Taxol at 80 mg/m², the patients to date who received TOCOSOL Paclitaxel had no Grade 2 through 4 neuropathy. This compares to an average rate of 17% in patients who received Taxol. In addition, incidences to date of other side effects, including neutropenia, were equal to or lower than the rates for Taxol.

A total of 73 patients were enrolled in the dose escalation stage of the Phase 2 studies, including 18 in each of the non-small cell lung, bladder and colorectal studies and 19 patients in the ovarian study. Preliminary efficacy data for these 73 patients show a disease control rate of 78% in non-small cell lung cancer, 89% in bladder cancer, 37% in ovarian cancer and 39% in colorectal cancer. These results include partial responses (decrease of tumor area of more than 50%) and stable disease (halting of tumor growth) at all of the dosing levels studied in the dose escalation stage from 80 mg/m² to 120 mg/m². The results to date are preliminary and may or may not be indicative of the final results upon completion of the Phase 2 studies. We continue to enroll additional patients in the Phase 2 studies.

We are currently in the process of evaluating protocols for additional clinical trials for certain of the four indications currently under study. We anticipate commencement of these trials in the United States in late 2002 or early 2003.

In addition to TOCOSOL Paclitaxel, we are also evaluating other products and additional therapeutic drug formulations to expand our TOCOSOL technology platform. The next product candidate in this group is a cancer therapy drug that we have named TOCOSOL Camptothecin, or S-9148. This product, which is a novel injectable formulation of camptothecin, is in late stage preclinical studies and we anticipate filing an IND with the FDA by the end of 2002. Our research and development efforts on potential new products are preliminary and we cannot give any assurance that our efforts will be successful or that any IND's will be filed.

In June 2002, the Company entered into a manufacturing and supply agreement with Gensia Sicor Pharmaceuticals, Inc. for TOCOSOL Paclitaxel. The purpose of the agreement is to provide the Company with a reliable manufacturer of the product for future clinical studies and commercialization requirements.

Results of Operations

Our results of operations have varied and will continue to vary significantly and depend on, among other factors:

- Entering into additional contractual agreements and timing of payments under contractual and license agreements with third-parties;
- Timing and costs of product development, clinical trials and patent prosecution; and
- Timing of regulatory approvals.

Historically, our reported revenues have been derived from payments received under contractual and license agreements with third parties. The Company reported no revenue in the third quarter of 2002 compared to \$7.6 million for the third quarter of 2001. Revenues for the third quarter of the prior

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year represent a payment of \$6.5 million related to the assignment of substantially all of our contrast intellectual property to Nycomed Amersham plc. (Nycomed) and a \$1.0 million non-refundable license fee payment received under an ultrasound contrast patent license agreement with Chugai Pharmaceutical Co. Ltd. (Chugai). For the nine months ended September 30, 2002, revenue was \$25,000 compared to \$8.7 million for the prior year period. Included in 2001 was a \$6.5 million payment from Nycomed and \$2.0 million in non-refundable license fee payments received under an ultrasound contrast patent license agreement with Chugai. Monetizing the remaining value of the ultrasound contrast intellectual property was a key strategic goal in the prior year.

Total operating expenses were \$3.4 million for the third quarter of 2002 compared with \$2.5 million for the prior year. The increase in operating expenses from the prior year was primarily due to higher research and development expenses (\$2.6 million in the third quarter of 2002 compared to \$1.3 million in the third quarter of 2001). This planned increase reflects continued activity related to the manufacture, development and clinical testing of our lead cancer therapy product, TOCOSOL Paclitaxel, as the drug advances through Phase 2 clinical trials as well as increased costs to support new product development. General and administrative expenses were lower (\$786,000 in the third quarter of 2002 compared to \$1.2 million in the third quarter of 2001) primarily due to higher personnel costs in the prior year period. For the first nine months of 2002, total operating expenses were \$9.6 million compared to \$6.3 million for the prior year period. The increase reflects the advancement of our lead product, TOCOSOL Paclitaxel, into phase 2 clinical trials and continued development costs of additional new drug compounds as we move to expand our product portfolio.

We anticipate that total operating expenses for the next several quarters will be within the same approximate range as the third quarter of 2002 as we continue to invest in current and future product development activities. Net cash burn for the full year 2002 is expected to be approximately \$13.0 to \$14.0 million.

Net interest income was \$104,000 and \$362,000 for the three and nine months ended September 30, 2002 compared with \$180,000 and \$418,000 for the same periods in 2001. The decrease in net interest income was primarily due to lower interest rates in the current year, offset partially by higher levels of invested cash in the current year.

Net loss for the third quarter of 2002 was \$3.3 million, compared with net income of \$5.2 million for the same period of the prior year. Net loss for the nine months ended September 30, 2002 was \$9.2 million compared with net income of \$2.7 million for the same period of the prior year.

Liquidity and Capital Resources

We have historically financed operations with payments under contractual agreements with third parties and proceeds from equity financings. At September 30, 2002, we had cash, cash equivalents and marketable securities of \$19.2 million compared to \$15.1 million at December 31, 2001. The increase was primarily due to \$12.5 million of net proceeds from a private placement of common stock in January 2002, offset in part by the year-to-date net loss of \$9.2 million.

We expect that our cash requirements will increase in future periods due to development costs associated with our TOCOSOL drug delivery products. Based on our current operating plan, including planned clinical trials and other product development costs including technology transfer costs related to our manufacturing and supply agreement, we estimate that existing cash and marketable securities will be sufficient to meet our cash requirements through 2003. However, we will need additional funding to complete late stage clinical trials and regulatory approval of TOCOSOL Paclitaxel and to fund other product development activities beyond this timeframe. Accordingly, we intend to seek additional funding through available means, which may include debt and/or equity financing or funding under additional third party collaborative agreements.

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Our future capital requirements depend on many factors including:

- The progress of our research and development programs and clinical trials;
- The time and costs required to complete clinical trials and obtain regulatory approvals;
- The ability to raise additional funds through debt and/or equity financing;
- The ability to attract and retain collaborative agreement partners;
- The time and costs required to complete the technology transfer associated with manufacturing and supply agreements;
- The ability to obtain funding under contractual and licensing agreements; and
- The costs of filing, prosecuting, enforcing and defending patents, patent applications, patent claims and trademarks.

We cannot give assurance that additional financing will be available on acceptable terms, if at all. Any equity financing would likely result in dilution to our existing stockholders and debt financing, if available, may include restrictive covenants. If we are unable to raise additional financing, we may be required to curtail or delay the development of our products and new product research and development, which could seriously harm our business.

Critical Accounting Policies and Estimates

The preparation of the financial statements requires management to make estimates and assumptions. On an on-going basis, management evaluates its estimates and judgements including those related to revenue recognition and research and development costs. Management bases its estimates and judgements on historical experience and on various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among others, affect its more significant judgements and estimates used in the preparation of its financial statements.

- *Revenue Recognition.* Since inception, the Company has generated revenues from collaborative agreements, licensing fees and from the assignment of developed and patented technology. Revenue is recorded as earned based on the performance requirements of the contract, generally as the services are performed. The Company recognizes revenue from non-refundable, up front license fees and proceeds from the assignment of technology when delivery has occurred and no future obligations exist. Royalties from licensees are based on third-party sales and recorded as earned in accordance with contract terms, when third-party results are reliably measured and collection is reasonably assured. Payments received for which the earnings process is not complete are classified as deferred revenue.
- *Research and Development Costs.* These items including personnel costs, supplies, depreciation and other indirect research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties for research and/or clinical trial activities, costs are expensed the earlier of when amounts are due or when services are performed.

Certain Factors That May Affect Our Business and Future Results

If we fail to develop products, then we may never realize revenue from product commercialization.

A key element of our business strategy is to utilize our technologies for the development and commercialization of drug delivery products. Our drug delivery technology, TOCOSOL, is a new approach to the formulation of water insoluble compounds for therapeutic applications. Significant expenditures in additional research and development, clinical testing, regulatory, manufacturing, and sales and marketing activities will be necessary in order for us to demonstrate the efficacy of our products, or commercialize any products developed with our technology. There can be no assurance that TOCOSOL Paclitaxel or any of our other current products under development or any future product will be safe or efficacious.

Even if we are successful in developing our products, there is no assurance that such products will receive regulatory approval or that a commercially viable market will develop. While it is our strategy to develop additional products under our drug delivery technology by entering into feasibility study agreements with companies who own active compounds, there can be no assurance that we will enter into any feasibility studies. Moreover, there can be no assurance that these feasibility studies will result in development or license agreements. Without feasibility studies or development or license agreements, we may need to scale back or terminate our efforts to develop other products using our drug delivery technology.

We have a history of operating losses, and we may never become profitable.

We have experienced significant accumulated losses since our inception, and are expected to incur net losses for the foreseeable future. These losses have resulted primarily from expenses associated with our research and development activities, including nonclinical and clinical trials, and general and administrative expenses. As of September 30, 2002, our accumulated deficit totaled \$37.9 million. We anticipate that our operating losses will continue as we further invest in research and development for our products. We will not generate any product revenues unless and until we receive regulatory approval, which will not occur in the near future. Even if we generate significant product revenues, there can be no assurance that we will be able to achieve or sustain profitability. Our results of operations have varied and will continue to vary significantly and depend on, among other factors:

- The timing and costs of clinical trials and regulatory approvals;
- Entering into new collaborative or product license agreements;
- The timing of payments, if any, under collaborative partner agreements; and
- Costs related to obtaining, defending and enforcing patents.

Governmental regulatory requirements are lengthy and expensive and failure to obtain necessary approvals will prevent us or our collaborators from commercializing a product.

We are subject to uncertain governmental regulatory requirements and a lengthy approval process for our products prior to any commercial sales of our products. The development and commercial use of our products are regulated by the U.S. Food and Drug Administration, or FDA, the European Medicines Evaluation Agency, or EMEA, and comparable regulatory agencies in other countries. The regulatory approval process for new products is lengthy and expensive. Before we can file an application with the FDA and comparable international agencies, the product candidate must undergo extensive testing, including animal studies and human clinical trials that can take many years and require substantial expenditures. Data obtained from such testing may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in

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regulatory policy for product approval may cause additional costs in our efforts to secure necessary approvals.

Our drug delivery products are subject to significant uncertainty because they are in the early stages of development and are subject to regulatory approval. We filed an Investigational New Drug Application, or IND, with the FDA for the first application of our TOCOSOL drug delivery technology and completed the Phase 1 clinical study of TOCOSOL Paclitaxel in May 2002. In March 2002, we initiated the first four Phase 2 clinical trials. There can be no assurance that the clinical studies will demonstrate that TOCOSOL Paclitaxel will be safe or efficacious or that we will file a new drug application. We are also currently engaged in pre-clinical testing of a formulation of our TOCOSOL drug delivery product using camptothecin. We expect to file an IND for TOCOSOL Camptothecin with the FDA by the end of 2002. The results of pre-clinical and clinical testing of our products are uncertain and regulatory approval of our products may take longer or be more expensive than anticipated, which could have a material adverse affect on our business, financial condition and results of operations. We cannot predict if or when any of our products under development will be commercialized.

We depend on third parties for funding, clinical development, manufacturing and distribution.

We are dependent, or 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. We currently do not have any arrangements with third parties in place which will provide any funding to the Company. If we are unable to establish these arrangements with third parties, if they are terminated or the collaborations are not successful, we will be required to identify alternative partners to fund or perform research, clinical development, manufacturing, marketing, sales and/or distribution, which could have a material adverse effect on our business, financial condition and results of operations. Our success depends in part upon the performance by these collaborators of their responsibilities under these arrangements. We have no control over the resources that any potential partner may devote to the development and commercialization of products under these collaborations and our partners may fail to conduct their collaborative activities successfully or in a timely manner.

We will need additional capital in the future, and if it is not available on terms acceptable to us, or at all, we may need to scale back our development and commercialization activities.

Our development efforts to date have consumed and will continue to require substantial amounts of cash, and we have generated only limited revenues from payments received from our contractual agreements and from the assignment of substantially all of our ultrasound contrast intellectual property. Based on our current operating plan, including planned clinical trials and other product development costs, we estimate that existing cash and marketable securities, will be sufficient to meet our cash requirements through 2003. However, we will need substantial additional capital to complete the development of TOCOSOL Paclitaxel as well as other product candidates and to meet our other cash requirements in the future. Our future capital requirements depend on many factors including:

- Our ability to obtain funding from third parties under contractual agreements;
- Our progress on research and development programs and clinical trials;
- The time and costs required to gain regulatory approvals;
- The costs of manufacturing our products;
- The costs of marketing and distributing our products, if approved;
- The costs of filing, prosecuting and enforcing patents, patent applications, patent claims and trademarks;
- The status of competing products; and
- The market acceptance and third-party reimbursement of our products, if approved.

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Any future equity financing, if available, may result in substantial dilution to existing stockholders, and debt financing, if available, may include restrictive covenants. If we are unable to raise additional financing, we may have to reduce our expenditures, scale back our development of new products or license to others products that we otherwise would seek to commercialize ourselves.

Future U.S. or international legislative or administrative actions also could prevent or delay regulatory approval of our products.

Even if regulatory approvals are obtained, they may include significant limitations on the indicated uses for which a product may be marketed. A marketed product also is subject to continual FDA, EMEA and other regulatory agency review and regulation. Later discovery of previously unknown problems or failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions. In addition, if marketing approval is obtained, the FDA, EMEA or other regulatory agency may require post-marketing testing and surveillance programs to monitor the product's efficacy and side effects. Results of these post-marketing programs may prevent or limit the further marketing of a product.

Failure to satisfy Nasdaq National Market Listing requirements may result in our stock being delisted from The Nasdaq National Market.

Our common stock is currently listed on The Nasdaq National Market under the symbol "SNUS." For continued inclusion on The Nasdaq National Market, we must maintain among other requirements stockholders' equity of at least \$10.0 million, a minimum bid price of \$1.00 per share, and a market value of our public float of at least \$5.0 million, or market capitalization of at least \$50 million, a minimum bid price of \$3.00 per share and a market value of our public float of at least \$15.0 million. As of September 30, 2002, we had stockholders' equity of \$18.1 million. In the event that we fail to satisfy the listing standards on a continuous basis, our common stock may be removed from listing on The Nasdaq National Market. If our common stock were delisted from The Nasdaq National Market, trading of our common stock, if any, would be conducted in the over-the-counter market in the so-called "pink sheets" or, if available, the NASD's "Electronic Bulletin Board." As a result, stockholders could find it more difficult to dispose of, or to obtain accurate quotations as to the value of, our common stock, and the trading price per share could be reduced.

The healthcare industry is extremely competitive, and if we fail to compete effectively, it would negatively impact our business.

The healthcare industry in general is characterized by extensive research efforts and rapid technological change. 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 in these fields will be based primarily on:

- Efficacy;
- Safety;
- Ease of administration;
- Breadth of approved indications; and
- Physician, healthcare payer and patient acceptance.

Several other companies are developing paclitaxel reformulations with a goal of delivering a more effective and tolerable therapy than the approved product, Taxol, marketed by Bristol-Myers Squibb, or its generic equivalents. In addition, Aventis has been successful in establishing its docetaxel product

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Taxotere™ in the breast cancer market. Some of these products are further in development than TOCOSOL Paclitaxel and may achieve regulatory approval before TOCOSOL Paclitaxel. We expect that competition will be based on safety, efficacy, ease of administration, breadth of approved indications, reimbursement, and physician and patient acceptance. As a result, the price for paclitaxel products has been falling.

Many of our competitors and potential competitors have substantially greater financial, technical and human resources than we do and have substantially greater experience in developing products, obtaining regulatory approvals and marketing and manufacturing medical products. Accordingly, these competitors may succeed in obtaining FDA approval for their products more rapidly than us. In addition, other technologies or products may be developed that have an entirely different approach that would render our technology and products noncompetitive or obsolete. If we fail to compete effectively, it would have a material adverse effect on our business, financial condition and results of operations.

We rely on third party suppliers and manufacturers to produce products that we develop and failure to retain such suppliers and manufacturers would adversely impact our ability to commercialize our products.

We currently rely on third parties to supply the chemical ingredients necessary for our drug delivery products. Currently, Indena is our primary supplier of paclitaxel, the main ingredient in TOCOSOL Paclitaxel. The chemical ingredients for our products are manufactured by a limited number of vendors. The inability of these vendors to supply medical-grade materials to us could delay the manufacturing of, or cause us to cease the manufacturing of our products. We also rely on third parties to manufacture our products for research and development and clinical trials. Gensia Sicor Pharmaceuticals, Inc. is our primary supplier of TOCOSOL Paclitaxel for clinical studies and has agreed to manufacture TOCOSOL Paclitaxel for commercialization. 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. If there are problems associated with the commercial scale-up of TOCOSOL Paclitaxel, it could delay our research and development efforts as well as the time it takes to commercialize our products, which could materially adversely affect our business, financial condition and results of operations.

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 November 2002, we had 2 patents issued and 25 patent applications filed in the United States pertaining to our TOCOSOL drug delivery technology as well as counterpart filings in Europe and key countries in Asia and Latin America. 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.

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Our commercial success will depend in part on not infringing patents issued to competitors.

There can be no assurance that patents belonging to competitors will not require us to alter our products or processes, pay licensing fees or cease development of our current or future products. Any litigation regarding infringement could result in substantial costs to us and distraction of our management, and any adverse ruling in any litigation could have a material adverse effect on our business, financial condition and results of operations. Further, there can be no assurance that we will be able to license other technology that we may require at a reasonable cost or at all. Failure by us to obtain a license to any technology that we may require to commercialize our products would have a material adverse effect on our business, financial condition and results of operations. In addition, to determine the priority of inventions and the ultimate ownership of patents, we may participate in interference, reissue or re-examination proceedings conducted by the U.S. Patent and Trademark Office or in proceedings before international agencies with respect to any of our existing patents or patent applications or any future patents or applications, any of which could result in loss of ownership of existing, issued patents, substantial costs to us and distraction of our management.

The success of our products will depend on the acceptance of our products by third party payers.

Our ability to successfully commercialize products that we develop will depend, in part, upon the extent to which reimbursement of the cost of such products will be available from domestic and international health administration authorities, private health insurers and other payer organizations. Third party payers are increasingly challenging the price of medical and pharmaceutical products and services or restricting the use of certain procedures in an attempt to limit costs. Further, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, and there can be no assurance that adequate third party coverage will be available.

If we lose our key personnel or are unable to attract and retain qualified scientific and management personnel, we may be unable to become profitable.

We are highly dependent on our key executives. The loss of any of these key executives or the inability to recruit and retain qualified scientific personnel to perform research and development and qualified management personnel could have a material adverse effect on our business, financial condition and results of operations. We do not have employment contracts with any of our key personnel and we do not maintain insurance policies that would compensate us for the loss of their services. There can be no assurance that we will be able to attract and retain such personnel on acceptable terms, if at all, given the competition for experienced scientists and other personnel among numerous medical and pharmaceutical companies, universities and research institutions.

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

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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. Accordingly, our common stock may be subject to greater price volatility than the stock market as a whole.

Item 3. Market Risk

The market risk inherent in our marketable securities portfolio represents the potential loss that could arise from adverse changes in interest rates. If market rates hypothetically increase immediately and uniformly by 100 basis points from levels at September 30, 2002, the decline in the fair value of the investment portfolio would not be material. Because we have the ability to hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates.

Item 4. Controls and Procedures

Within 90 days prior to the date of this quarterly report, we carried out an evaluation, 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. There were no significant changes to our internal controls or in other factors that could significantly affect such internal controls subsequent to the date that we carried out our evaluation.

Part II. Other Information

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

- | | |
|------|--|
| 99.1 | Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 99.2 | Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

(b) Reports on Form 8-K

The Company filed no reports on Form 8-K during the quarter ended September 30, 2002.

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

SIGNATURES

In accordance with the requirements of the Securities Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SONUS PHARMACEUTICALS, INC

Date: November 13, 2002

By: /s/ Richard J. Klein

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

CERTIFICATIONS

I, Michael A. Martino, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sonus Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ Michael A. Martino

Michael A. Martino
President and Chief
Executive Officer

CERTIFICATIONS

I, Richard J. Klein, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Sonus Pharmaceuticals, Inc.;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures 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 quarterly report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
 - c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ Richard J. Klein

Richard J. Klein
Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS
ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

I, Michael A. Martino, President and Chief Executive Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2002 (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 operation of the Company.

Dated: November 13, 2002

/s/ Michael A. Martino

Michael A. Martino
President and Chief Executive Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS
ADOPTED PURSUANT TO SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002

I, Richard J. Klein, Chief Financial Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2002 (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 operation of the Company.

Dated: November 13, 2002

/s/ Richard J. Klein

Richard J. Klein
Chief Financial Officer