SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004

Or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES AND EXCHANGE ACT OF 1934 (NO FEE REQUIRED)

Commission File Number 0-26866

Sonus Pharmaceuticals, Inc.

(Exact name of the registrant as specified in its charter)

Delaware	**95-4343413**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

22026 20th Avenue SE, Bothell, Washington 98021
(Address of principal executive offices)

(425) 487-9500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:
Not Applicable

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.001 per share
Series A Junior Participating Preferred Stock, par value $0.001 per share

Indicate by check mark 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 report), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

As of June 30, 2004, the aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant was $100,108,074. As of March 8, 2005, 21,352,795 shares of the registrant's Common Stock were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed in connection with the solicitation of proxies for its 2005 Annual Meeting of Stockholders to be held on May 25, 2005 are incorporated by reference in Items 10, 11, 12, 13 and 14 of Part III hereof.

Sonus Pharmaceuticals, Inc.
Table of Contents

PART I

References in this Form 10-K to "Sonus Pharmaceuticals", "Sonus", the "Company", "we", "us" or "our" refer to Sonus Pharmaceuticals, Inc. The information in this Form 10-K contains certain forward-looking statements, including statements related to clinical trials, regulatory approvals, markets for the Company's products, capital requirements and trends in its business that involve risks and uncertainties. The Company's actual results may differ materially from the results discussed in the forward-looking statements. Factors that might cause such a difference include those discussed in "Business", "Certain Factors that May Affect Our Business and Future Results" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as those discussed elsewhere in this Form 10-K.

ITEM 1. BUSINESS

Overview

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

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

On December 22, 2004, we executed an Amended and Restated Stock Purchase Agreement with the stockholders of Synt:em S.A. for the purchase of all of the outstanding capital stock of Synt:em. On March 15, 2005, we delivered an irrevocable notice to the Chief Executive Officer of Synt:em, S.A., pursuant to Sections 8.1(e) and 8.2 the Amended and Restated Stock Purchase Agreement terminating the Amended and Restated Stock Purchase Agreement effective March 31, 2005.

In reaching our conclusion to terminate the Amended and Restated Stock Purchase Agreement, management weighed the increased human and financial resources required to take advantage of opportunities with TOCOSOL® Paclitaxel, our lead oncology candidate, against the human and financial resources required to complete the transaction and subsequent integration of the Synt:em S.A. business with our business. We concluded that the best course of action was to focus our resources on opportunities with TOCOSOL® Paclitaxel and remain as a standalone company.

According to the terms of the Amended and Restated Stock Purchase Agreement, properly terminating the Amended and Restated Stock Purchase Agreement pursuant to Section 8.1(e) will not result in any material early termination penalties or financial liability to us. Through December 31, 2004, we incurred approximately $1.0 million in legal, accounting and investment banker fees on this transaction. These charges are reflected in our 2004 financial statements as general and administrative expense. We anticipate that we will incur an additional $100,000 to $200,000 in legal, accounting and investment banker fees in 2005 for work done subsequent to December 31, 2004.

TOCOSOL Technology Platform

Our proprietary TOCOSOL technology platform has been designed to address the formulation challenges of hard-to-formulate therapeutic drugs for cancer. Development of drug products with our TOCOSOL technology may result in products with equivalent or better efficacy, decreased incidences of side effects and dosing convenience. The TOCOSOL technology uses vitamin E oil (α-tocopherol) and tocopherol derivatives to

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

TOCOSOL Paclitaxel

Our lead oncology candidate, TOCOSOL Paclitaxel, is a novel formulation of paclitaxel, one of the world's most widely prescribed anti-cancer drugs. Paclitaxel, a member of the taxane family of cancer drugs, is the active ingredient in Taxol®, which is approved in the U.S. for the treatment of breast, ovarian and non-small cell lung cancers and Kaposi's sarcoma. Our product, TOCOSOL Paclitaxel, is a ready-to-use, injectable paclitaxel emulsion formulation. We believe that data from our clinical trials conducted to date suggest that TOCOSOL Paclitaxel compares favorably with approved taxane products and other new paclitaxel formulations under development (safety and efficacy remain to be proven in Phase 3 testing); offers the convenience of a ready-to-use formulation that does not require time consuming preparation prior to administration; can be administered to patients by a short 15-minute infusion, compared to the one- to three-hour infusion that is typically required with Taxotere® and Taxol or generic versions of paclitaxel; does not require any special intravenous, or IV tubing, filters or other apparatus; and does not require reconstitution or dilution, which results in administration of small volumes of 25 to 35 milliliters compared to several hundred milliliters for Taxol.

We concluded a Phase 1 study for TOCOSOL Paclitaxel in August 2002, with a total of 37 patients. The objectives of the Phase 1 study were to estimate the maximum tolerated dose of TOCOSOL Paclitaxel in patients with advanced cancers, and to evaluate the safety of repeated doses of TOCOSOL Paclitaxel given every three weeks. In the Phase 1 study, 30 of the 37 patients were treated at doses ranging from 175 mg/m^2 to 225 mg/m^2 every three weeks. The maximum tolerated dose (MTD) was estimated in this study to be 200 mg/m^2 every three weeks, slightly higher than the approved dose of Taxol at 175 mg/m^2 every three weeks. TOCOSOL Paclitaxel was generally well tolerated in all patients treated. All patients in the Phase 1 study had advanced cancers that were no longer responding to previous therapies or for which no standard therapy existed. Five patients with different types of cancers had objective partial responses during the course of the study, including four patients who had previously been treated with taxane-containing chemotherapy regimens (under the RECIST criteria, partial response is defined as reduction in the sum of the longest tumor dimensions of target lesions of ³30% for at least four weeks, and no evidence of progressive disease elsewhere). Dose-limiting toxicities included myalgia (muscle aches), fatigue, and neutropenia (low neutrophilic white blood cell count). No Grade 4 neuropathy (damage to the peripheral nerves) was seen at or below the estimated MTD in the Phase 1 study.

We initiated Phase 2a studies for TOCOSOL Paclitaxel in March 2002 to evaluate the safety and efficacy of TOCOSOL Paclitaxel in ovarian, non-small cell lung and bladder cancers using weekly dosing of the product. These were single agent, open label studies that enrolled patients who had progressive disease despite prior treatment with one standard chemotherapy regimen, but who had not previously received taxane chemotherapy. Each Phase 2a study began with a dose escalation phase to estimate the best tolerated dose of TOCOSOL Paclitaxel using weekly administration. The best tolerated dose was initially estimated to be 120 mg/m² per week in the ovarian and lung cancer trials, and 100 mg/m² per week in the bladder cancer trial, based on observations among a small number of patients treated for a few weeks. However, subsequent retrospective review of actual doses administered across all patients in all studies over extended treatment periods has suggested that patients assigned to receive weekly doses of 100 mg/m² or 120 mg/m² actually received similar cumulative doses over time.

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. A total of 120 patients in the ovarian, non-small cell lung and bladder cancer studies were evaluable for objective response, which means that the patients received at least eight weekly cycles of TOCOSOL Paclitaxel and had at least one CT scan to confirm anti-tumor responses according to the RECIST criteria.

In the ovarian cancer study, 51 enrolled patients were evaluable for anti-tumor effect. Twenty of the 51 evaluable patients (39%) were reported as having objective responses, including three complete responses (under the RECIST criteria, complete response is defined as no evidence of remaining tumor, confirmed on two CT scans

at least four weeks apart) and 17 partial responses; 16 additional patients were reported to have stable disease (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).

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

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

The Phase 2a investigator-reported efficacy results are summarized in the table below:

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

In addition to being assessed for anti-tumor efficacy, patients are also monitored for adverse events in clinical studies. The most significant adverse events expected with taxanes are neutropenia and peripheral neuropathy. The incidence of Grade 3 or Grade 4 neutropenia across all the Phase 2a studies conducted was 36%. No peripheral neuropathy was observed in 63% of patients, Grade 3 peripheral neuropathy was reported in only 10% of patients, and no patients experienced Grade 4 peripheral neuropathy in the Phase 2a studies. We believe these adverse event rates compare favorably to the reported neutropenia and peripheral neuropathy experienced when Taxol is administered at the approved dose of 175 mg/m^2 every three weeks. Dose reductions or treatment delays due to toxicity from TOCOSOL Paclitaxel did not limit long-term treatment in most patients. At the highest dose tested, 120 mg/m^2 weekly, approximately 70% of planned doses were delivered on schedule at full dose, for a median weekly dose over time of 105 mg/m^2. At the 100 mg/m^2 dose level, approximately 84% of doses were delivered on schedule at full dose, for a median weekly dose of 96 mg/m^2. Paclitaxel-mediated infusion reactions, sometimes called "hypersensitivity reactions" and involving pain, flushing, shortness of breath or chest tightness, were infrequently observed following more than 2,200 administered doses. Only 15% of doses led to a reaction of any severity, and only 1% of doses led to reactions that were of Grade 3 severity, i.e., requiring supportive treatment. There were no Grade 4 infusion reactions. Again, we believe these frequencies compare favorably with reported rates of infusion reactions upon administration of Taxol. Investigators have reported that infusion reactions with our product could be ameliorated by temporary (a few minutes) interruption of infusion, while corticosteroid premedications were not helpful. Infusion reactions very rarely prevented delivery of intended doses. Overall, we believe that TOCOSOL Paclitaxel appears to be well tolerated over multiple treatment cycles.

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. As of March 4, 2005, investigators reported an overall objective response rate in the mid 30% to 40% range, and 35 patients remained on active treatment. We expect to be able to estimate the median time to progression in the third quarter of this year and evaluation will continue throughout the next two years.

The results of the Phase 2a and 2b clinical trials are preliminary at this time and have not been independently verified by third party radiologists and may or may not be indicative of the final results upon completion of the these studies or of the results of our planned Phase 3 study that is yet to be initiated.

Our objective is to advance the final clinical development, gain marketing approval and then maximize the commercial opportunity of TOCOSOL Paclitaxel. We have outlined a regulatory strategy for TOCOSOL Paclitaxel that includes three potential development paths. Our goal with the regulatory strategy is to gain the

fastest possible market entry with a competitive label, while in parallel pursuing opportunities to expand the label indications to further differentiate the product. Our strategy for product approval includes.

- *505(b)(2).* We will seek initial approval of TOCOSOL Paclitaxel with a 505(b)(2) New Drug Application ("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 ingredients that are already well known. As part of our regulatory strategy, we initiated a randomized crossover clinical pharmacology study in the fourth quarter of 2003, to compare the amount of paclitaxel delivered into circulation over time by TOCOSOL Paclitaxel and Taxol, with both drugs given at 175 mg/m^2 every three weeks (the approved dosing regimen for Taxol). We completed patient enrollment in March 2004 and final data were available for analysis in September 2004. The data from this study indicate that TOCOSOL Paclitaxel delivers substantially more active paclitaxel into circulation than can be achieved with 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. In September 2004, Sonus Pharmaceuticals requested and was subsequently granted a meeting with the FDA to discuss its plans for Phase 3 testing of TOCOSOL Paclitaxel. Sonus met with the FDA in December 2004, and based on preclinical and clinical data generated to date, the FDA indicated that it is appropriate for Sonus to pursue Phase 3 testing and submission of a TOCOSOL Paclitaxel New Drug Application under a 505(b)(2) regulatory mechanism. In addition, the FDA recommended that Sonus finalize the design and plan of the TOCOSOL Paclitaxel Phase 3 program under a Special Protocol Assessment ("SPA"), which the Company plans to pursue. Our original guidance for the possible timing of submission of an NDA, seeking approval of TOCOSOL Paclitaxel based on a single confirmatory efficacy trial, was that it might occur as early as late 2005 or early 2006. While we have agreement in concept from the FDA on the use of a single Phase 3 trial, we do not believe that it will be possible to submit the NDA by the end of 2005 or possibly even early 2006 per our original guidance.

- *New indication for taxanes.* Under this component of our strategy, we will pursue approval for the use of TOCOSOL Paclitaxel as a treatment for inoperable or metastatic urothelial transitional cell cancers (mostly urinary bladder cancers), an indication for which there is an unmet medical need for an effective, less toxic therapy. In October 2003, we announced that we were granted Fast Track designation by the FDA for the development of TOCOSOL Paclitaxel for this indication. We initiated a Phase 2b study in bladder cancer in the U.S. using weekly dosing of TOCOSOL Paclitaxel in the fourth quarter of 2003. 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. As previously indicated, we are opening additional study sights in Europe to augment enrollment in this trial. In December 2004, the FDA also granted an Orphan Drug designation to TOCOSOL Paclitaxel for the treatment of non-superficial urothelial cancer.

- *Life cycle management.* We intend to conduct trials in other types of cancer, for which paclitaxel given once every three weeks is already approved, to support labeling of TOCOSOL Paclitaxel for weekly treatment of those diseases or to use higher doses of TOCOSOL Paclitaxel given every three weeks, potentially leading to greater anti-tumor efficacy. The data from such clinical trials could support Supplemental New Drug Applications (SNDAs) following a 505(b)(2) NDA, if successful. We initiated a Phase 2b study in breast cancer during the third quarter of 2004.

The scope, timing and expense of the clinical trials to be conducted under all of the above regulatory strategies are difficult to determine with accuracy until these clinical trials are specifically approved by the FDA. At this time it is our intent to pursue a single pivotal trial in an indication where Paclitaxel is approved as a single

agent, with a primary endpoint of objective response rate and secondary endpoints of time to progression and survival duration. We expect to submit the NDA with data on the primary endpoint, followed by supplemental applications when data are mature for the secondary endpoints. We intend the trial to be powered to achieve statistical significance on all three endpoints, which may require us to enroll approximately 700 to 800 patients. We estimate that the total cost to complete the proposed Phase 3 clinical trial for TOCOSOL Paclitaxel and submission of a TOCOSOL Paclitaxel NDA under a 505(b)(2) regulatory mechanism over a period of about three years will be in the mid to upper $30 million range. Should our clinical data support an NDA submission based on the primary endpoint of objective response rates, we anticipate that the NDA could be submitted within twelve months after conclusion of patient enrollment. This trial constitutes the bulk of our clinical trial spending anticipated in the next 12 months. 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 submit an NDA for TOCOSOL Paclitaxel. There can be no assurance that the results of any or all of the anticipated clinical trials will be successful or will support an approved product. The completion of any and all of the anticipated clinical trials is dependent upon our receipt of additional financing, either through debt or equity offerings of our securities or through a corporate or strategic partnership.

If we are unable to secure a corporate partner or raise additional financing in 2005 and beyond through other means, we will have to substantially reduce our expenditures, delay the enrollment of patients in our Phase 3 clinical trial for TOCOSOL Paclitaxel, scale back the development of our other products and new product research and development and reduce personnel costs. In addition, we would likely have to out license products that we otherwise would seek to commercialize ourselves, which could seriously harm our business, and cause us to explore other strategic alternatives.

Research and Development Pipeline

We continue to invest in the research and development of new product candidates, including those that we believe could extend the application of our TOCOSOL technology platform. We are currently evaluating early stage therapeutic drug formulations utilizing the TOCOSOL technology, including potential product candidates based on the camptothecin molecule. The camptothecin molecule family is poorly soluble and difficult to formulate for administration to humans. There are currently two marketed hydrophilic (water-based) camptothecin analogs that are based on chemical modifications to the camptothecin molecule. Irinotecan, which is marketed under the name Camptosar®, is indicated for treatment of colorectal cancer. Topotecan, which is marketed under the name Hycamtin®, is indicated for treatment of ovarian and non-small cell lung cancers. Our research and development efforts on these camptothecin product candidates are preliminary and we cannot give any assurance that any of these compounds will be successful or that they will progress to clinical trials. Advancing one or more of these development candidates into human clinical trials is dependent on several factors including technological feasibility and commercial opportunity.

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

Market Overview

Cancer is characterized by rapid, uncontrolled cell division resulting in the growth of an abnormal mass of cells generally referred to as a tumor. Cancerous tumors can arise in almost any tissue or organ, and cancer cells, if not eradicated, can spread, or metastasize, throughout the body. As these tumors grow, they cause damage to the surrounding tissue and organs and commonly result in death if left untreated. Cancer is believed to occur as a result of a number of hereditary and environmental factors. According to the American Cancer Society, cancer is the second leading cause of death in the United States and accounts for approximately one in every four deaths.

Approximately 570,000 Americans are expected to die of cancer in 2005. The National Institutes of Health estimated the direct medical cost of cancer to be $69 billion in 2004.

Our lead product candidate, TOCOSOL Paclitaxel, is a cancer therapy drug. Paclitaxel, the active ingredient in TOCOSOL Paclitaxel, is a member of the taxane class of chemotherapy drugs, which generate annual worldwide sales in excess of $2 billion. TOCOSOL Paclitaxel, if approved, would address only a portion of this market depending on the approved indication(s). Other products in our pipeline are for the most part, in the early

stages of development, and it is difficult to evaluate the potential markets for these products as the areas of potential application are diverse and specific applications are yet to be determined.

Manufacturing

We originally used the University of Iowa as the FDA-certified institution to manufacture TOCOSOL Paclitaxel under current Good Manufacturing Practice ("GMP") requirements for our use in preclinical and clinical studies. In mid-2002, we entered into a manufacturing and supply agreement with SICOR Pharmaceuticals, Inc. The SICOR agreement has an initial term of five years after the market introduction of TOCOSOL Paclitaxel, provided that market introduction occurs before June 2009, and is not terminable at will. During 2003, in collaboration with SICOR, we completed scaling of the drug product manufacturing process for TOCOSOL Paclitaxel to commercial levels under current GMP requirements, ensuring adequate clinical drug supplies for ongoing and planned clinical trials, and providing a commercial scale process to enable regulatory approval and product launch. On the material supply side, we have entered into agreements for the supply of GMP-grade paclitaxel, which is the active pharmaceutical ingredient in TOCOSOL Paclitaxel.

Research and Development

We currently conduct research and development activities at our facilities in Bothell, Washington. We also engage in certain research, preclinical studies and clinical development efforts at third party laboratories and other institutions. Our primary research and development efforts are currently directed at the development and application of the TOCOSOL technology with respect to TOCOSOL Paclitaxel and to a lesser extent, other various compounds to which the technology can bring advantage.

Our research and development activities for the last three years can be divided into research and preclinical programs and clinical development programs primarily for the treatment of cancer. The costs associated with research and preclinical programs and clinical development programs for the last three fiscal years were as follows *(in millions)*:

	2004	2003	2002
Research and preclinical programs	$ 5.8	$ 4.9	$ 5.0
Clinical development programs	$ 4.9	$ 2.8	$ 4.0
Total research and development	$ 10.7	$ 7.7	$ 9.0

Because of the number of research projects we have ongoing at any one time, and the ability to utilize resources across several projects, the majority of our research and development costs are not directly tied to any individual project and are allocated among multiple projects. We manage our projects by reviewing scientific data and by supplementing these data with our cost allocations. Our cost allocations are based primarily on human resource time incurred on each project. As a result, the costs allocated to a project do not necessarily reflect the actual cash costs of the project. Accordingly, we do not maintain actual cost incurred information for our projects on a project-by-project basis. Costs attributed to research and preclinical projects largely represent our pipeline generating activities. Costs associated with clinical development programs represent the advancement of these activities into testing of product candidates in humans. See Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" for further discussion of research and development spending trends.

Government Regulations – Drug Approval Process

Regulation by governmental authorities in the U.S. and other countries is a significant factor in our ongoing research and development activities and in the production and marketing of our products. In order to undertake clinical tests, to produce and market products for human diagnostic use, mandatory procedures and safety standards established by the FDA in the U.S. and comparable agencies in other countries must be followed.

The standard process required by the FDA before a pharmaceutical agent may be marketed in the U.S. includes the following steps:

(i) Preclinical studies including laboratory evaluation and animal studies to test for initial safety and efficacy;
(ii) Submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human clinical trials in the U.S. may commence;
(iii) Adequate and well-controlled clinical trials to establish the safety and efficacy of the drug in its intended population and use(s);
(iv) Submission to the FDA of a New Drug Application, or NDA, which application is not automatically accepted by the FDA for consideration; and
(v) FDA approval of the NDA prior to any commercial sale or shipment of the drug.

In addition to obtaining FDA approval for each product, each domestic drug-manufacturing establishment must be registered by the FDA for each product that is manufactured at that facility. U.S. manufacturing establishments are subject to inspections by the FDA and by other federal, state and local agencies and must comply with GMP requirements applicable to the production of pharmaceutical drug products. 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.

Preclinical studies include laboratory evaluation of the active drug substance and its formulation in animal studies to assess the potential safety and efficacy of the drug and its formulation. Prior to initiating the first clinical testing of a new drug product candidate, the results of the preclinical studies are submitted to the FDA as part of an IND, and unless the FDA objects, the IND will become effective 30 days following its receipt by the FDA.

Clinical trials involve the administration of the investigational drug product to healthy volunteers and/or to patients with a defined disease state, under the supervision of a qualified principal investigator. In the case of cytotoxic drugs, such as TOCOSOL Paclitaxel, all clinical trials are conducted only in eligible patients with cancer. Clinical trials are conducted in accordance with protocols that detail the objectives of the study, the parameters to be used to monitor safety and the efficacy criteria to be evaluated. Each protocol is submitted to the FDA as part of the IND. Each clinical study is approved and monitored by one or more independent Institutional Review Boards or Ethics Committees who consider, among other things, ethical factors, informed consent documents, the safety of human subjects and the possible liability of the institutions conducting a clinical study. The Institutional Review Board or Ethics Committee may require changes in the clinical trials protocol, which may delay initiation or completion of the study.

Clinical trials typically are conducted in three sequential phases, although the phases may overlap. In Phase 1, the initial introduction of the drug to humans, the drug is tested for safety and clinical pharmacology. Phase 2 trials involve more detailed evaluation of the safety and efficacy of the drug in patients with the disease or condition being studied. Phase 3 trials consist of large scale evaluations of safety and efficacy compared to accepted standard therapy and typically require multiple clinical trial sites.

The process of completing clinical testing and obtaining FDA approval for a new product takes a number of years and requires the expenditure of substantial resources. The FDA may grant full approval of a drug product for a particular indication or may grant approval conditioned on further post-marketing clinical trials. The FDA also may conclude that the NDA is not adequate to support an approval and may require further clinical and preclinical testing, re-submission of the NDA, and further review. Even after initial FDA approval has been obtained, further studies may be required to provide additional data about the approved indication, and further studies will be required to gain approval for the use of a product for clinical indications other than those for which

the product was approved initially. Also, the FDA may require post-marketing testing and surveillance programs to monitor the drug product's side effects.

Marketing of pharmaceutical products outside of the U.S. is subject to regulatory requirements that vary from country to country. In the European Union, the general trend has been towards coordination of common standards for clinical testing of new drug products. Centralized approval in the European Union is coordinated through the European Medicines Evaluation Agency, or EMEA.

The level of regulation outside of the U.S. and European Union varies widely. The time required to obtain regulatory approval from regulatory agencies in each country may be longer or shorter than that required for FDA or EMEA approval. In addition, in certain markets, reimbursement may be subject to governmentally mandated prices.

Many of the chemicals and compounds used in our research and development efforts are classified as hazardous materials under applicable federal, state and local environmental laws and regulations. We are subject to regulations under state and federal law regarding occupational safety, laboratory practices, handling and disposing of chemicals, environmental protection and hazardous substance control. We also will be subject to other possible future regulations of local, state, federal and other jurisdictions.

Competition

The healthcare industry in general is characterized by extensive research efforts, rapid technological change and intense competition. We believe that other pharmaceutical companies will compete with us in areas of research and development, acquisition of products and technology licenses, and the manufacturing and marketing of products that could potentially compete with ours. We expect that competition will be based on safety, efficacy, ease of administration, breadth of approved indications, price, reimbursement and physician and patient acceptance.

Several other companies are developing paclitaxel reformulations with a goal of delivering a more effective and tolerable therapy than Taxol and the approved generic paclitaxel-based products. Some of these products are further in development than TOCOSOL Paclitaxel and may achieve regulatory approval before our product. On January 7, 2005, American Pharmaceutical Partners obtained FDA approval to market its Paclitaxel-based product, Abraxane® (paclitaxel protein-bound particles for injectible suspension). In addition, Aventis has a taxane product, Taxotere (docetaxel), which has a similar mechanism of action to paclitaxel and is marketed for the treatment of breast and non-small cell lung cancers. There are also a number of generic formulations of 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.

We believe that our ability to successfully compete in the biotechnology and pharmaceutical industries will be based on our ability to do the following:

- Create and maintain advanced formulation technologies;
- Develop proprietary products;
- Attract and retain key scientific personnel;
- Obtain patent or other protection for products;
- Obtain required regulatory approvals; and
- Manufacture, market and or license our products alone or with collaborative partners.

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 products. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before their competitors may achieve a significant competitive advantage if their products work through a similar mechanism as our products. 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.

Patents and Proprietary Rights

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 16, 2005, seven United States patents and two patents outside the U.S., one in Canada and one in Taiwan, have issued pertaining to our TOCOSOL technology platform. 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 advantage or will not be challenged by third parties, or that 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 or administrative proceedings may be necessary to enforce any patents issued to us or to determine the scope and validity of others' proprietary rights.

Our commercial success will depend in part on not infringing patents issued to competitors. There can be no assurance that patents belonging to competitors or others will not require us to alter our products or processes, pay licensing fees or cease development of our current or future products. 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 have a material adverse effect on our business, financial condition and results of operations.

We have obtained registration for our mark TOCOSOL®, in the United States. There can be no assurance that the registered or unregistered trademarks or trade names of our company will not infringe upon third party rights or will be acceptable to regulatory agencies.

We also rely on unpatented trade secrets, proprietary know-how and continuing technological innovation, which we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants in our drug development research. There can be no assurance that these agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets or know-how will not otherwise become known or be independently discovered by competitors. Further, there can be no assurance that we will be able to protect our trade secrets or that others will not independently develop substantially equivalent proprietary information and techniques.

Product Liability

The clinical testing, manufacturing and marketing of our products may expose us to product liability claims. We maintain liability insurance for possible claims arising from the use of our products in clinical trials with limits of $5.0 million per claim and in the aggregate, which we believe to be adequate for the current non-commercial applications of our products. We do anticipate increasing this coverage upon enrollment of patients in our Phase 3 clinical trial for TOCOSOL Paclitaxel. The incremental coverage requirements and costs are yet to be determined. Although we have never been subject to a product liability claim, there can be no assurance that the coverage limits of our insurance policies will be adequate or that one or more successful claims brought against us would not have a material adverse effect upon our business, financial condition and results of operations. If any of our products under development gain marketing approval from the FDA, there can be no assurance that adequate product liability insurance will be available, or if available, that it will be available at a

reasonable cost. Any adverse outcome resulting from a product liability claim could have a material adverse effect on our business, financial condition and results of operations.

Employees

As of March 8, 2005, we had 47 employees, 32 engaged in research and development, regulatory, clinical and manufacturing activities, and 15 in business operations and administration. All of our employees are covered by confidentiality agreements. We consider our relations with our employees to be good, and none of our employees is a party to a collective bargaining agreement.

Certain Factors That May Affect Our Business and Future Results

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

We expect that our cash requirements will continue to increase in future periods due to development costs associated with TOCOSOL Paclitaxel and other product candidates. We do expect to see a decline in G&A expenses in 2005, as 2004 included the majority of the costs related to the terminated Synt:em acquisition. Based on our 2005 operating plan, which includes certain cost reductions, we estimate that existing cash, cash equivalents and marketable securities will be sufficient to meet our cash requirements through at least the end of first quarter 2006. We intend to raise at least $10.0 million in additional cash through debt or equity financing or pursuant to a corporate partnership in 2005, to permit us to proceed with certain of our product development efforts, which are currently not included in the 2005 operating plan. We are seeking a corporate partnership to proceed with the enrollment of patients in the Phase 3 clinical trial of TOCOSOL Paclitaxel. If we are unable to raise additional cash in 2005 through either a debt or equity financing or pursuant to a corporate partnership by the end of the second quarter 2005, we will continue our scaled back 2005 operating plan such that we would have sufficient cash to fund our operations through at least the first quarter of 2006. Under this assumption, the required scale back would be significant and would involve programs, operations and personnel which would materially impact our ability to initiate the Phase 3 clinical trial for TOCOSOL Paclitaxel as well as advance our other product candidates along in development. Our current balance of cash and marketable securities should enable us to proceed with the development and testing of TOCOSOL Paclitaxel up to the point of patient enrollment in the Phase 3 clinical trial. Enrollment of patients in the Phase 3 trial cannot occur until we have additional funding either through a corporate partner or other type of financing. In addition to funding planned in 2005, we will need additional capital to complete the development of TOCOSOL Paclitaxel and other product candidates. We estimate that the total cost to complete the Phase 3 clinical trial for TOCOSOL Paclitaxel and submission of a TOCOSOL Paclitaxel New Drug Application under a 505(b)(2) regulatory mechanism over a period of three years will be in the mid to upper $30 million range. However, until we agree upon an SPA with the FDA, the scope and structure of the Phase 3 clinical trial is uncertain and 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 submit a New Drug Application for TOCOSOL Paclitaxel. Should our clinical data support an NDA submission based on the primary endpoint of objective response rates, we anticipate that the NDA could be submitted within twelve months after conclusion of patient enrollment. Our future capital requirements depend on many factors including:

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

Any future debt or equity financing, if available, may result in substantial dilution to existing stockholders, and debt financing, if available, may include restrictive covenants. If we are unable to raise additional financing in 2005 and beyond, we will have to substantially reduce our expenditures, scale back the development of our products and new product research and development and reduce our personnel costs. In addition, we would likely have to out license products that we otherwise would seek to commercialize ourselves, which could seriously harm our business, and cause us to explore other strategic alternatives.

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

A key element of our business strategy is to utilize our technologies for the development and commercialization of products that utilize our TOCOSOL technology platform. Most of our attention and resources are directed to the development of TOCOSOL, a technology that provides a novel approach to the formulation of water insoluble compounds for therapeutic applications. Significant expenditures in additional research and development, clinical testing, regulatory, manufacturing, and sales and marketing activities will be necessary in order for us to demonstrate the efficacy of our products, or commercialize any products developed with our technology. There can be no assurance that TOCOSOL based products under development or any future products will be safe or efficacious. If the TOCOSOL based products under development are ultimately ineffective in treating cancer, do not receive the necessary regulatory approvals or do not obtain commercial acceptance, we will incur additional losses, our accumulated deficit will increase and our business will be materially adversely affected.

Even if we are successful in developing our products, there is no assurance that such products will receive regulatory approval or that a commercially viable market will

develop.

We have a history of operating losses which we expect will continue and we may never become profitable.

We have experienced significant accumulated losses since our inception, and are expected to incur net losses for the foreseeable future. These losses have resulted primarily from expenses associated with our research and development activities, including nonclinical and clinical trials, and general and administrative expenses. As of December 31, 2004, our accumulated deficit totaled $67.1 million. We anticipate that our operating losses will continue as we further invest in research and development for our products. We will not generate any product revenue unless and until we receive regulatory approval, which is not likely to occur in the near future. Even if we generate significant product revenue, there can be no assurance that we will be able to achieve or sustain profitability. Our results of operations have varied and will continue to vary significantly and depend on, among other factors:

- our ability to obtain, and timing of payments, if any, under corporate partner agreements or other financing;
- timing and costs of preclinical development, clinical trials and regulatory approvals;
- drug discovery and research & development;
- timing and costs of technology transfer associated with manufacturing and supply agreements; and
- costs related to obtaining, defending and enforcing patents.

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

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

susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. In addition, changes in regulatory policy for product approval may cause additional costs in our efforts to secure necessary approvals.

Our product candidates are subject to significant uncertainty because they are in both early and middle stages of development and are subject to regulatory approval. The results of preclinical and clinical testing of our products are uncertain and regulatory approval of our products may take longer or be more expensive than anticipated, which could have a material adverse effect on our business, financial condition and results of operations. While the FDA has informally indicated that it is appropriate for Sonus to submit a TOCOSOL Paclitaxel NDA under a 505(b)(2) regulatory mechanism using a single Phase 3 clinical trial, there can be no assurance that the FDA will agree to our proposed 505(b)(2) regulatory strategy and Phase 3 protocol until such time that we have an executed SPA in place with them. 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 depend on third parties for funding, clinical development, manufacturing and distribution.

We are dependent, and may in the future be dependent, on third parties for funding or performance of a variety of key activities including research, clinical development, manufacturing, marketing, sales and distribution of our products. Our current business strategy is to enter into agreements with third parties both to license rights to our potential products and to develop and commercialize new products. We currently do not have any arrangements with third parties that 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 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 any potential partner may devote to the development and commercialization of products under these potential collaborations and our partners may fail to conduct their collaborative activities successfully or in a timely manner.

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

We are highly dependent on our key executives, including Michael A. Martino, President & Chief Executive Officer, Michael B. Stewart, Senior Vice President & Chief Medical Officer and Alan Fuhrman, Senior Vice President & Chief Financial Officer. We do not have employment agreements in place with these key executives nor do we maintain any key person life insurance coverage on these persons. The loss of any of these key executives or the inability to recruit and retain qualified scientific personnel to perform research and development and qualified management personnel could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that we will be able to attract and retain such personnel on acceptable terms, if at all, given the competition for experienced scientists and other personnel among numerous medical and pharmaceutical companies, universities and research institutions.

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

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

The development of pharmaceutical products in general and the development of paclitaxel reformulations in particular is extremely competitive, and if we fail to compete effectively, it would negatively impact our business.

Competition in the development of pharmaceutical products is intense and expected to increase. We also believe that other medical and pharmaceutical companies will compete with us in the areas of research and development, acquisition of products and technology licenses, and the manufacturing and marketing of our products. Success of

products in these fields will be based primarily on:

- efficacy;
- safety;
- price;
- ease of administration;
- breadth of approved indications; and
- physician, healthcare payor and patient acceptance.

Several other companies are developing paclitaxel reformulations with a goal of delivering a more effective and tolerable therapy than the approved paclitaxel products. Some of these products are further in development than TOCOSOL Paclitaxel and may achieve regulatory approval before our product. On January 7, 2005, American Pharmaceutical Partners obtained FDA approval to market its Paclitaxel-based product, Abraxane® (paclitaxel protein-bound particles for injectible suspension). In addition, Aventis has a taxane product, Taxotere, which is similar to paclitaxel and is marketed for the treatment of breast and non-small cell lung cancers. As a result of the increased competition, the price for paclitaxel products has been under pressure and may drop significantly even if we achieve regulatory approval.

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

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

We currently rely on third parties to supply the chemical ingredients necessary for our drug product candidates. We have entered into supply agreements for the supply of GMP grade paclitaxel, which is the active pharmaceutical ingredient in TOCOSOL Paclitaxel. The chemical ingredients for our products are manufactured by a limited number of vendors. The inability of these vendors to supply medical-grade materials to us could delay the manufacturing of, or cause us to cease the manufacturing of our products. We also rely on third parties to manufacture our products for research and development and clinical trials. SICOR Pharmaceuticals, Inc. is our

primary manufacturer of TOCOSOL Paclitaxel for clinical studies and has also agreed to manufacture TOCOSOL Paclitaxel for commercialization. The SICOR 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 16, 2005, seven United States patents and two patents outside the U.S., one in Canada and one in Taiwan, have issued pertaining to our TOCOSOL technology platform. Additional patent applications are pending in the United States and counterpart filings have been made in Europe, Canada and key countries in Asia and Latin America. The patent position of medical and pharmaceutical companies is highly uncertain and involves complex legal and factual questions. There can be no assurance that any claims which are included in pending or future patent applications will be issued, that any issued patents will provide us with competitive advantages or will not be challenged by third parties, or that the existing or future patents of third parties will not have an adverse effect on our ability to commercialize our products. Furthermore, there can be no assurance that other companies will not independently develop similar products, duplicate any of our products or design around patents that may be issued to us. Litigation may be necessary to enforce any patents issued to us or to determine the scope and validity of others' proprietary rights in court or administrative proceedings. Any litigation or administrative proceeding could result in substantial costs to us and distraction of our management. An adverse ruling in any litigation or administrative proceeding could have a material adverse effect on our business, financial condition and results of operations.

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

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

Reimbursement procedures and future healthcare reform measures are uncertain and may adversely impact our ability to successfully sell pharmaceutical products.

Our ability to successfully sell any pharmaceutical products will depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse patients for the costs of future pharmaceutical products and related treatments. In the United States, government and other third-party payors have sought to contain healthcare costs by limiting both coverage and the level of reimbursement for new pharmaceutical products approved for marketing by the FDA. In some cases, these payors may refuse to provide any coverage for uses of approved products to treat medical conditions even though the FDA has granted marketing approval. Healthcare reform may increase these cost containment efforts. We believe that managed care organizations may seek to restrict the use of new products, delay

authorization to use new products or limit coverage and the level of reimbursement for new products. Internationally, where national healthcare systems are prevalent, little if any funding may be available for new products, and cost containment and cost reduction efforts can be more pronounced than in the United States.

If our products are not accepted by the medical community our business will suffer.

Commercial sales of our proposed products will substantially depend upon the products' efficacy and on their acceptance by the medical community. Widespread acceptance of our products will require educating the medical community as to the benefits and reliability of the products. Our proposed products may not be accepted, and, even if accepted, we are unable to estimate the length of time it would take to gain such acceptance.

The businesses in which we engage have a risk of product liability, and in the event of a successful suit against us, our business could be severely harmed.

The testing, marketing and sale of pharmaceutical products entails a risk of product liability claims by consumers and others. While we currently maintain product liability insurance for our clinical trials with limits of $5 million per claim in the aggregate, which we believe to be adequate for current non-commercial and pre-Phase 3 applications of our products, such insurance may not continue to be available at a reasonable cost for large scale clinical trials or commercial applications, or may not be sufficient to fully cover any potential claims. In the event of a successful suit against us, the lack or insufficiency of insurance coverage could have a material adverse effect on our business and financial condition.

Since we use hazardous materials in our business, we may be subject to claims relating to improper handling, storage or disposal of these materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts.

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

Our common stock is currently listed on The Nasdaq National Market under the symbol "SNUS." For continued inclusion on The Nasdaq National Market, we must maintain among other requirements stockholders' equity of at least $10.0 million, a minimum bid price of $1.00 per share and a market value of our public float of

at least $5.0 million; or market capitalization of at least $50 million, a minimum bid price of $3.00 per share and a market value of our public float of at least $15.0 million. As of December 31, 2004, we had stockholders' equity of approximately $19.1 million. In the event that we fail to satisfy the listing standards on a continuous basis, our common stock may be removed from listing on The Nasdaq National Market. If our common stock were delisted from The Nasdaq National Market, our common stock may be transferred to the Nasdaq SmallCap Market if we satisfy the listing criteria for the Nasdaq SmallCap Market or trading of our common stock, if any, may be conducted in the over-the-counter market in the so-called "pink sheets" or, if available, the National Association of Securities Dealer's "Electronic Bulletin Board." In addition, delisting from Nasdaq may subject our common stock to so-called "penny stock" rules. These rules impose additional sales practice and market making requirements on broker-dealers who sell and/or make a market in such securities. Consequently, broker-dealers may be less willing or able to sell and/or make a market in our common stock. Additionally, an investor would find it more difficult to dispose of, or to obtain accurate quotations for the price of, our common stock. As a result of a delisting, it may become more difficult for us to raise funds through the sale of our securities.

Market volatility may affect our stock price and the value of an investment in our common stock may be subject to sudden decreases.

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, preclinical and clinical trial results, market perception of the prospects for biotechnology companies as an industry sector and general market and economic conditions, some of which are beyond our control. Factors such as fluctuations in our financial and operating results, changes in government regulations affecting product approvals, reimbursement or other aspects of our or our competitors' businesses, FDA review of our product development activities, the results of preclinical studies and clinical trials, announcements of technological innovations or new commercial products by us or our competitors, developments concerning key personnel and our intellectual property rights, significant collaborations or strategic alliances and publicity regarding actual or potential performance of products under development by us or our competitors could also cause the market price of our common stock to fluctuate substantially. In addition, the stock market has from time to time experienced extreme price and volume fluctuations. These broad market fluctuations may lower the market price of our common stock. Moreover, during periods of stock market price volatility, share prices of many biotechnology companies have often fluctuated in a manner not necessarily related to the companies' operating performance. Also, biotechnology or pharmaceutical stocks may be volatile even during periods of relative market stability. Accordingly, our common stock may be subject to greater price volatility than the stock market as a whole.

Company Information

Sonus Pharmaceuticals was incorporated in California in October 1991 and subsequently reorganized as a Delaware corporation in September 1995. The Company's principal executive offices are located at 22026 20th Avenue SE, Bothell, Washington 98021, and its telephone number is (425) 487-9500. The Company makes its annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports available on its website, at http://www.sonuspharma.com, free of charge as soon as practicable after filing with the SEC. All such reports are also available free of charge via EDGAR through the SEC website at www.sec.gov. In addition, the public may read and copy materials filed by the Company with the SEC at the SEC's public reference room located at 450 Fifth St., N.W., Washington, D.C., 20549. Information regarding operation of the SEC's public reference room can be obtained by calling the SEC at 1-800-SEC-0330.

ITEM 2. PROPERTIES

We currently lease approximately 27,000 square feet of laboratory and office space in a single facility near Seattle, Washington. The lease expires in July 2007 and includes an option to extend the term of the lease for three years. We believe that this facility will be adequate to meet our projected needs for the foreseeable future and that our monthly rent is reflective of current market rates.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may be involved in litigation relating to claims arising out of our operations in the normal course of business. The Company currently is not a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on the Company's results of operations or financial position.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2004.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK

Our common stock first began trading on the Nasdaq National Market under the symbol SNUS on October 12, 1995. No cash dividends have been paid on the common stock, and we do not anticipate paying any cash dividends in the foreseeable future. As of March 8, 2005, there were 250 stockholders of record and approximately 5,700 beneficial stockholders of our Common Stock. The high and low sales prices of our common stock as reported by Nasdaq National Market for the periods indicated are as follows:

	High	Low
2003		
First Quarter	$ 2.75	$ 1.90
Second Quarter	4.32	1.95
Third Quarter	6.45	3.45
Fourth Quarter	6.26	4.55
2004		
First Quarter	$ 8.81	$ 5.00
Second Quarter	7.64	3.67
Third Quarter	4.76	2.97
Fourth Quarter	3.95	2.15
2005		
First Quarter (through 3/8/05)	$ 4.50	$ 3.20

ITEM 6. SELECTED FINANCIAL DATA

The data set forth below should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements and Notes thereto appearing at Item 8 of this report.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
	(in thousands, except per share data)				
Statements of Operations Data:					
Revenue	$ —	$ 25	$ 25	$ 8,749	$ 408
Operating expenses	$ 16,576	$ 10,663	$ 12,199	$ 8,532	$ 7,641
Net income (loss)	$ (16,311)	$ (10,467)	$ (11,636)	$ 542	$ (2,147)
Net income (loss) per share:					
Basic	$ (0.81)	$ (0.68)	$ (0.86)	$ 0.05	$ (0.23)
Diluted	$ (0.81)	$ (0.68)	$ (0.86)	$ 0.05	$ (0.23)
Shares used in calculation of net income (loss) per share					
Basic	20,169	15,504	13,564	10,288	9,146
Diluted	20,169	15,504	13,564	11,048	9,146

	December 31,				
	2004	2003	2002	2001	2000
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 20,580	$ 19,664	$ 16,334	$ 15,124	$ 8,462
Total assets	$ 22,571	$ 21,468	$ 17,934	$ 15,864	$ 14,310
Long-term liabilities	$ 238	$ 364	$ 518	$ —	$ —
Stockholders' equity	$ 19,077	$ 19,310	$ 15,724	$ 14,665	$ 8,509

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

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

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

While these forward-looking statements made by us are based on our current beliefs and judgments, they are subject to risks and uncertainties that could cause actual results to vary from the projections in the forward-looking statements. You should consider the risks below carefully in addition to other information contained in this

report before engaging in any transaction involving shares of our common stock. If any of these risks occur, they could seriously harm our business, financial condition or results of operations. In such case, the trading price of our common stock could decline, and you may lose all or part of your investment.

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

- future capital requirements and uncertainty of additional funding through either debt or equity financings or corporate partnerships;
- dependence on the development and commercialization of products;
- future prospects heavily dependent on results of TOCOSOL Paclitaxel;
- history of operating losses and uncertainty of future financial results;
- uncertainty of governmental regulatory requirements and lengthy approval process;
- dependence on third parties for funding, clinical development, manufacturing and distribution;
- 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;
- continued listing on the Nasdaq National Market; and
- volatility in the value of our common stock.

MD&A Overview

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

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

Business Overview

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

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

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

Subsequent Event: Termination of Material Definitive Agreement

On December 22, 2004, we executed an Amended and Restated Stock Purchase Agreement with the stockholders of Synt:em S.A. for the purchase of all of the outstanding capital stock of Synt:em. On March 15, 2005, we delivered an irrevocable notice to the Chief Executive Officer of Synt:em, S.A., pursuant to Sections 8.1(e) and 8.2 the Amended and Restated Stock Purchase Agreement terminating the Amended and Restated Stock Purchase Agreement effective March 31, 2005.

In reaching our conclusion to terminate the Amended and Restated Stock Purchase Agreement, management weighed the increased human and financial resources required to take advantage of opportunities with TOCOSOL® Paclitaxel, our lead oncology candidate, against the human and financial resources required to complete the transaction and subsequent integration of the Synt:em S.A. business with our business. We concluded that the best course of action was to focus our resources on opportunities with TOCOSOL® Paclitaxel and remain as a standalone company.

According to the terms of the Amended and Restated Stock Purchase Agreement, properly terminating the Amended and Restated Stock Purchase Agreement pursuant to Section 8.1(e) will not result in any material early termination penalties or financial liability to us. Through December 31, 2004, we incurred approximately $1.0 million in legal, accounting and investment banker fees on this transaction. These charges are reflected in our 2004 financial statements as general and administrative expense. We anticipate that we will incur an additional $100,000 to $200,000 in legal, accounting and investment banker fees in 2005 for work done subsequent to December 31, 2004.

Results of Operations

As of December 31, 2004, our accumulated deficit was approximately $67.1 million. We expect to incur substantial additional operating losses over the next several years. Such losses have been and will continue to principally be the result of various costs associated with our discovery and research and development programs. Substantially all of our working capital in recent years has resulted from equity financings. Historically, substantially all of our revenue has resulted from corporate partnerships and licensing arrangements. Our ability to achieve a consistent, profitable level of operations depends in large part on entering into corporate partnerships for product discovery, research, development and commercialization, obtaining regulatory approvals for our

products and successfully manufacturing and marketing our products once they are approved. Even if we are successful in the aforementioned activities our operations may not be profitable. In addition, payments under corporate partnerships and licensing arrangements are subject to significant fluctuations in both timing and amount. Therefore, our operating results for any period may fluctuate significantly and may not be comparable to the operating results for any other period.

Years Ended December 31, 2004 and December 31, 2003

We had no revenue for the year ended December 31, 2004 as compared with $25,000 for 2003.

Our research and development (R&D) expenses were $10.7 million for the year ended December 31, 2004 compared with $7.7 million for 2003. The 2004 increase was primarily the result of the expansion of clinical trial programs in support of the anticipated Phase 3 clinical trial for TOCOSOL Paclitaxel. We expect R&D expenses to increase substantially in 2005 upon commencement of our Phase 3 clinical trial for TOCOSOL Paclitaxel.

Our general and administrative (G&A) expenses were $5.9 million for the year ended December 31, 2004 compared with $3.0 million for 2003. The 2004 increase was primarily attributed to approximately $1.0 million in costs related to the termination of our acquisition of Synt:em as well as increased personnel, business development and Sarbanes-Oxley compliance costs in 2004. We expect G&A expenses for 2005 to decrease by approximately $1.0 million from the 2004 levels as the majority of the expenses related to the terminated Synt:em agreement were recognized in 2004.

Our total operating expenses in 2005 are expected to increase from 2004 levels as we move into Phase 3 clinical development of TOCOSOL Paclitaxel. We estimate that R&D spending will comprise approximately 75%-80% of the anticipated spending in 2005, assuming we are successful in raising additional financing. 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. Additionally, we will be required to substantially reduce our anticipated R&D expenses if additional financing is not available in 2005.

Our interest income, net of interest expense, was $265,000 for the year ended December 31, 2004 compared with $171,000 for 2003. The 2004 increase was due primarily to higher levels of invested cash in 2004.

The Company had no income tax expense in 2004 or 2003 as it had incurred significant losses and has significant net operating loss carryforwards.

Years Ended December 31, 2003 and December 31, 2002

Our revenue was unchanged at $25,000 for the years ended December 31, 2003 and 2002.

Our R&D expenses were $7.7 million for the year ended December 31, 2003 compared with $9.0 million for 2002. The 2003 decrease as compared with 2002 reflected the completion of patient enrollment in the Phase 2a clinical trials in mid-2003.

Our G&A expenses were $3.0 million for the year ended December 31, 2003, or slightly below the 2002 expense of $3.2 million.

Our interest income, net of interest expense, was $171,000 for the year ended December 31, 2003 compared with $437,000 for 2002. The 2003 decrease as compared with 2002 was primarily due to lower interest rates as well as lower levels of invested cash in 2003.

The Company had no income tax expense in 2003. During 2002, income taxes reflect a one-time tax benefit of $101,000 primarily related to regulatory changes in federal tax regulations in early 2002.

Liquidity and Capital Resources

We have historically financed operations with proceeds from equity financings and payments under contractual agreements with third parties. At December 31, 2004, we had cash, cash equivalents and marketable securities totaling $20.6 million compared to $19.7 million at December 31, 2003. The increase was primarily due to the $14.4 million in net proceeds from the private placement of 2.9 million shares of common stock in May 2004, $1.4 million in proceeds from the issuance of 345,000 shares of common stock from the exercise of common stock warrants and $259,000 in proceeds from the issuance of 151,000 shares of common stock under employee benefit programs. These increases were offset in part by the net loss for 2004 of $16.3 million.

Net cash used in operating activities for the years ended December 31, 2004, 2003, and 2002 was $14.6 million, $9.9 million and $10.4 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. Our G&A expenses are relatively controllable, although for the year ended December 31, 2004, we incurred approximately $1.0 million in legal, accounting and investment banker fees related to the terminated Synt:em acquisition. We estimate that we will incur an additional $100,000 to $200,000 in legal, accounting and investment banker fees in the first half of 2005 for work done subsequent to December 31, 2004 related to the terminated Synt:em acquisition. Our R&D expenses are dependent upon the scope of our clinical trial activities. We recognized no material revenues in any of the years presented and paid no corporate income taxes. We received a refund of approximately $70,000 in 2002 related primarily to changes in federal tax regulations for the treatment of net operating losses for alternative minimum taxes paid in prior years.

Net cash used in investing activities for the years ended December 31, 2004, 2003, and 2002 was $2.6 million, $2.7 million and $2.4 million, respectively. These uses of cash were primarily related to purchases and maturities of short-term investments and purchases of property and equipment 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.

Net cash provided by financing activities for the years ended December 31, 2004, 2003, and 2002 was $16.0 million, $13.9 million and $12.8 million, respectively. These inflows were primarily the result of private placement transactions by us in each of the years presented. We issued 2.9 million, 3.9 million and 1.9 million shares for the years ended December 31, 2004, 2003 and 2002, respectively under these transactions. We have used this type of equity financing to provide working capital for our operations over the last three years.

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 do expect to see a decline in G&A expenses in 2005, as 2004 included the majority of the costs related to the terminated Synt:em acquisition. Based on our 2005 operating plan, which includes certain cost reductions, we estimate that existing cash, cash equivalents and marketable securities will be sufficient to meet our cash requirements through at least the end of first quarter 2006. We intend to raise at least $10.0 million in additional cash through debt or equity financing or pursuant to a corporate partnership in 2005, to permit us to proceed with certain of our product development efforts, which are currently not included in the 2005 operating plan. We are seeking a corporate partnership to proceed with the enrollment of patients in the Phase 3 clinical trial of TOCOSOL Paclitaxel. If we are unable to raise additional cash in 2005 through either a debt or equity financing or pursuant to a corporate partnership by the end of the second quarter 2005, we will continue our scaled back 2005 operating plan such that we would have sufficient cash to fund our operations through at least the first quarter of 2006. Under this assumption, the required scale back would be significant and would involve programs, operations and personnel which would materially impact our ability to initiate the Phase 3 clinical trial for TOCOSOL Paclitaxel as well as advance our other product candidates along in development. Our current balance of cash and marketable securities should enable us to proceed with the development and testing of TOCOSOL Paclitaxel up to the point of patient enrollment in the Phase 3 clinical trial. Enrollment of patients in the Phase 3 trial cannot occur until we have additional funding either through a corporate partner or other type of financing. In addition to funding planned in 2005, we will need additional capital to complete the

development of TOCOSOL Paclitaxel and other

product candidates. We estimate that the total cost to complete the Phase 3 clinical trial for TOCOSOL Paclitaxel and submission of a TOCOSOL Paclitaxel New Drug Application under a 505(b)(2) regulatory mechanism over a period of three years will be in the mid to upper $30 million range. However, until we agree upon an SPA with the FDA, the scope and structure of the Phase 3 clinical trial is uncertain and 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 submit a New Drug Application for TOCOSOL Paclitaxel. Should our clinical data support an NDA submission based on the primary endpoint of objective response rates, we anticipate that the NDA could be submitted within twelve months after conclusion of patient enrollment. Our future capital requirements depend on many factors including:

- our ability to obtain and timing of payments, if any, under corporate partner agreements and/or debt or equity financings;
- timing and costs of preclinical development, clinical trials and regulatory approvals;
- drug discovery and research & development;
- entering into new collaborative or product license agreements;
- timing and costs of technology transfer associated with manufacturing and supply agreements; and
- costs related to obtaining, defending and enforcing patents.

Any future debt or equity financing, if available, may result in substantial dilution to existing stockholders, and debt financing, if available, may include restrictive covenants. If we are unable to raise additional financing in 2005 and beyond, we will have to substantially reduce our expenditures, scale back the development of our products and new product research and development and reduce personnel costs. In addition, we would likely have to out license products that we otherwise would seek to commercialize ourselves, which could seriously harm our business, and cause us to explore other strategic alternatives.

We have contractual obligations in the form of capital leases, operating leases and leasehold financing arrangements. We have remaining contractual obligations through 2007 under our operating leases of $1.8 million and $131,000 under our capital lease and leasehold financing agreements. The following table summarizes our contractual obligations, including interest as of December 31, 2004:

	Obligations due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Capital lease/lease financing obligations	$ 130,868	$ 85,279	$ 45,589	$ —	$ —
Operating lease obligations	1,815,664	686,928	1,128,736	—	—
Total:	$ 1,946,532	$ 772,207	$ 1,174,325	$ —	$ —

Critical Accounting Policies and Estimates

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

- *Revenue Recognition.* Since inception, the Company has generated revenue from collaborative agreements, licensing fees and from the assignment of developed and patented technology. We have recognized this revenue primarily through up-front, milestone and licensing payments. We recognize license revenue from intellectual technology agreements. Generally, the payments received under these

research collaboration agreements are contractually not refundable even if the research effort is not successful. Performance under our collaborative agreements is measured by scientific progress, as mutually agreed upon by us and our collaborators.

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

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

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

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

- *Research and Development Expenses.* Pursuant to SFAS No. 2 "Accounting for Research and Development Costs," our research and development costs are expensed as incurred. In instances where the Company enters into collaborative agreements with third parties, costs are expensed the earlier of when amounts are due or when services are performed. 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. Research and development expenses include, but are not limited to, payroll and personnel expenses, lab expenses, clinical trial and related clinical manufacturing costs, facilities and overhead costs.

- *Use of Estimates.* Our discussion and analysis of our financial condition and results of operations is based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and

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

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R "Share Based Payment." This statement is a revision to SFAS 123 and supersedes Accounting Principles Board (APB) Opinion No. 25, "Accounting for Stock Issued to Employees," and amends FASB Statement No. 95, "Statement of Cash Flows." This statement requires a public entity to expense the cost of employee services

received in exchange for an award of equity instruments. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. This statement is effective for the first interim reporting period that begins after June 15, 2005.

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

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

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

As permitted by SFAS 123, we currently account for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. The impact of the adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, valuation of employee stock options under SFAS 123R is similar to SFAS 123, with minor exceptions. For information about what our reported results of operations and earnings per share would have been had we adopted SFAS 123, please see the discussion under the heading "Stock Based Compensation" in Note 1 to our Financial Statements. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. Due to timing of the release of SFAS 123R, we have not yet completed the analysis of the ultimate impact that this new pronouncement will have on the results of operations, nor the method of adoption for this new standard.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The market risk inherent in our marketable securities portfolio represents the potential loss arising from adverse changes in interest rates. If market rates hypothetically increase immediately and uniformly by 100 basis points from levels at December 31, 2004, 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS:

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Sonus Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Sonus Pharmaceuticals, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Sonus Pharmaceuticals, Inc. at December 31, 2004 and 2003, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Sonus Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2005 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

Seattle, Washington
March 16, 2005

Sonus Pharmaceuticals, Inc.
Balance Sheets

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 416,847	$ 1,709,017
Marketable securities	20,163,641	17,954,578
Other current assets	458,826	147,084
Total current assets	21,039,314	19,810,679
Equipment, furniture and leasehold improvements, net	1,479,785	1,606,061
Other assets	51,500	51,500
Total assets	$ 22,570,599	$ 21,468,240
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,176,709	$ 1,642,947
Current portion of lease obligations	78,445	151,369
Total current liabilities	3,255,154	1,794,316
Lease obligations, less current portion	42,172	120,617
Deferred rent	196,092	243,624
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.001 par value:		
5,000,000 shares authorized; no shares outstanding	—	—
Common stock, $.001 par value:		
75,000,000 shares authorized; 21,352,795 and 17,957,452 shares issued and outstanding in 2004 and 2003, respectively	86,202,180	70,085,299
Accumulated deficit	(67,090,356)	(50,779,764)
Accumulated other comprehensive (loss) income	(34,643)	4,148
Total stockholders' equity	19,077,181	19,309,683
Total liabilities and stockholders' equity	$ 22,570,599	$ 21,468,240

See accompanying notes.

Sonus Pharmaceuticals, Inc.
Statements of Operations

	Year Ended December 31, 2004	2003	2002
Revenue:			
Contract and licensing revenue	$ —	$ 25,000	$ 25,000
Operating expenses:			
Research and development	10,706,223	7,653,486	8,956,755
General and administrative	5,869,331	3,009,665	3,242,342
Total operating expenses	16,575,554	10,663,151	12,199,097
Operating loss	(16,575,554)	(10,638,151)	(12,174,097)
Interest income (expense):			
Interest income	289,587	213,188	468,480
Interest expense	(24,625)	(42,136)	(31,667)
Total interest income, net	264,962	171,052	436,813
Loss before income taxes	(16,310,592)	(10,467,099)	(11,737,284)
Income tax benefit	—	—	101,483
Net loss	$ (16,310,592)	$ (10,467,099)	$ (11,635,801)
Net loss per share:			
Basic	$ (0.81)	$ (0.68)	$ (0.86)
Diluted	$ (0.81)	$ (0.68)	$ (0.86)

Shares used in calculation of net loss per share:			
Basic	20,169,258	15,503,794	13,563,754
Diluted	20,169,258	15,503,794	13,563,754

See accompanying notes.

Sonus Pharmaceuticals, Inc.
Statements of Stockholders' Equity

	Common Stock		Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Deficit	Income (Loss)	Total
Balance at December 31, 2001	11,650,797	$ 43,302,286	$ (28,676,864)	$ 39,708	$ 14,665,130
Comprehensive income (loss):					
Net loss	—	—	(11,635,801)	—	(11,635,801)
Unrealized losses on investments	—	—	—	(14,065)	(14,065)
Comprehensive loss					(11,649,866)
Issuance of common stock under employee benefit plans	111,750	432,314	—	—	432,314
Issuance of common stock and common stock warrants (net of offering costs of $1,293,100)	1,929,000	12,276,350	—	—	12,276,350
Balance at December 31, 2002	13,691,547	56,010,950	(40,312,665)	25,643	15,723,928
Comprehensive income (loss):					
Net loss	—	—	(10,467,099)	—	(10,467,099)
Unrealized losses on investments	—	—	—	(21,495)	(21,495)
Comprehensive loss					(10,488,594)
Issuance of common stock under employee benefit plans	98,725	191,746	—	—	191,746
Exercise of common stock warrants	237,109	728,893	—	—	728,893
Issuance of common stock and common stock warrants (net of offering costs of $1,082,977)	3,930,071	13,153,710	—	—	13,153,710
Balance at December 31, 2003	17,957,452	70,085,299	(50,779,764)	4,148	19,309,683
Comprehensive income (loss):					
Net loss	—	—	(16,310,592)	—	(16,310,592)
Unrealized losses on investments	—	—	—	(38,791)	(38,791)
Comprehensive loss					(16,349,383)
Issuance of common stock under employee benefit plans	150,628	259,093	—	—	259,093
Exercise of common stock warrants	344,715	1,409,884	—	—	1,409,884
Issuance of common stock (net of offering costs of $777,096)	2,900,000	14,447,904	—	—	14,447,904
Balance at December 31, 2004	21,352,795	$ 86,202,180	$ (67,090,356)	$ (34,643)	$ 19,077,181

See accompanying notes.

Sonus Pharmaceuticals, Inc.
Statements of Cash Flows

	Year Ended December 31,		
	2004	2003	2002
Operating activities:			
Net loss	$ (16,310,592)	$ (10,467,099)	$ (11,635,801)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	552,277	390,965	358,139
Amortization of net premium (discount) on marketable securities	(36,798)	(10,539)	222,480
Changes in operating assets and liabilities:			
Other current assets	(311,742)	91,325	53,148
Accounts payable and accrued expenses	1,533,762	130,566	356,024
Other liabilities	(47,532)	(44,782)	246,210
Net cash used in operating activities	(14,620,625)	(9,909,564)	(10,399,800)
Investing activities:			
Purchases of capital equipment	(426,001)	(686,636)	(904,933)
Purchases of marketable securities	(31,830,775)	(21,876,067)	(28,234,997)
Proceeds from sales of marketable securities	8,198,719	1,386,530	6,751,664
Proceeds from maturities of marketable securities	21,421,000	18,480,000	19,959,632
Net cash used in investing activities	(2,637,057)	(2,696,173)	(2,428,634)
Financing activities:			
Proceeds from issuance of common stock and common stock warrants under equity financings	14,447,904	13,153,710	12,276,350

Proceeds from exercise of common stock warrants	1,409,884	728,893	—
Proceeds from issuance of common stock under employee benefit plans	259,093	191,746	432,314
Payments on lease obligations	(151,369)	(137,602)	(81,766)
Proceeds from lease obligations	—	—	124,470
Net cash provided by financing activities	15,965,512	13,936,747	12,751,368
Change in cash and cash equivalents for the year	(1,292,170)	1,331,010	(77,066)
Cash and cash equivalents at beginning of year	1,709,017	378,007	455,073
Cash and cash equivalents at end of year	$ 416,847	$ 1,709,017	$ 378,007
Supplemental cash flow information:			
Interest paid	$ 24,625	$ 42,136	$ 31,667
Income taxes received	$ —	$ —	$ (70,078)
Supplemental disclosure of non-cash financing activity:			
Assets acquired under capital leases	$ —	$ —	$ 366,885

See accompanying notes.

Sonus Pharmaceuticals, Inc.
Notes to Financial Statements

1. Description of Business and Summary of Accounting Policies

Business Overview

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

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

Liquidity

The Company has historically experienced recurring losses from operations through December 31, 2004, which has generated an accumulated deficit of $67.1 million. In 2004, the Company used $14.6 million of cash to fund operations for the year. At December 31, 2004, the Company has cash and cash equivalents and marketable securities of $20.6 million, and working capital of $17.8 million.

The Company expects that its cash requirements will continue to increase in future periods due to the projected development costs associated with TOCOSOL Paclitaxel and other product candidates. Based on the 2005 operating plan, which includes certain cost reduction initiatives, the Company estimates that existing cash, cash equivalents and marketable securities will be sufficient to meet its cash requirements through at least the end of first quarter of 2006.

The Company also intends to raise at least $10.0 million in additional cash through a debt or equity financing or pursuant to a corporate partnership in 2005, to permit it to proceed with certain of its product development efforts, which are currently not included in the 2005 operating plan. The Company is seeking a corporate partnership to proceed with the enrollment of patients in the Phase 3 clinical trial of TOCOSOL Paclitaxel. The Company cannot be certain that such additional financing or corporate partnership will be available at acceptable terms, or at all.

If the Company is unable to raise additional cash in 2005 through either debt or equity financing or pursuant to a corporate partnership by the end of the second quarter of 2005, the Company will continue its scaled back 2005 operating plan such that it would have sufficient cash to fund its operations through at least the end of first quarter 2006. Under this assumption, the required operations scale back would be significant, and would involve reductions in programs, operations and personnel which would materially impact the Company's ability to advance product candidates along in development.

Cash and Cash Equivalents

Cash and cash equivalents consist of highly liquid investments with a maturity of three months or less at the date of purchase.

Marketable Securities

The Company classifies the marketable securities portfolio as available-for-sale, and such securities are stated at fair value based on quoted market prices, with the unrealized gains and losses included as a component of accumulated other comprehensive loss. Interest earned on securities available-for-sale is included in interest

income. The carrying value of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest income. Realized gains and losses and declines in value judged to be other than temporary on securities available-for-sale also are included in interest income. The cost of securities sold is based on the specific identification method.

Concentrations of Credit Risk

The Company invests its excess cash in accordance with investment guidelines, which limit the credit exposure to any one financial institution and to any one type of investment, other than securities issued by the U.S. government. The guidelines also specify that the financial instruments are issued by institutions with strong credit ratings. These securities are generally not collateralized and mature within one year.

Revenue Recognition

Since inception, the Company has generated revenue from collaborative agreements, licensing fees and from the assignment of developed and patented technology. Revenue is recorded as earned based on the performance requirements of the contract, generally as the services are performed. The Company recognizes revenue from non-refundable, upfront 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

Research and development costs including personnel costs, supplies, depreciation and other indirect costs are expensed as incurred. In instances where the Company enters into collaborative agreements with third parties, costs are expensed the earlier of when amounts are due or when services are performed. 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.

Equipment, Furniture and Leasehold Improvements

Equipment, furniture and leasehold improvements are stated at cost. Depreciation of equipment is provided using the straight-line basis over three to five years, the estimated useful life of the assets. Leasehold improvements are amortized over the lesser of the economic useful lives of the improvements or the term of the related lease. Repair and maintenance costs are expensed as incurred.

Stock-Based Compensation

Under the provisions of SFAS No. 123, *"Accounting for Stock-Based Compensation,"* companies may continue to follow Accounting Principles Board Opinion No. 25 (APB 25) in accounting for stock-based compensation and provide footnote disclosure of the pro forma impact of expensing stock options. We have elected to follow the disclosure-only provisions of SFAS No. 123 and continue to apply APB 25 and related interpretations in accounting for our stock option plans. Under the provisions of APB 25 and related interpretations, employee stock-based compensation expense is recognized based on the intrinsic value of the option on the date of grant (the difference between the market value of the underlying common stock on the date of grant and the option exercise price, if any).

At December 31, 2004 we had several stock-based employee compensation plans, which are described more fully in Note 5. All options granted under these plans had exercise prices equal to the market value of the underlying common stock on the date of grant and therefore, in accordance with APB 25, no stock-based employee compensation cost has been recorded.

As required under SFAS 123, the following table illustrates the effect on net loss and net loss per share if we had applied the fair value expense recognition provision of SFAS 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	2004	2003	2002
Net loss, as reported	$ (16,310,592)	$ (10,467,099)	$ (11,635,801)
Add: Stock-based employee compensation expense included in reported net loss	—	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(1,528,401)	(976,056)	(651,199)
Pro forma net loss	$ (17,838,993)	$ (11,443,155)	$ (12,287,000)
Loss per share:			
Basic and diluted-as reported	$ (0.81)	$ (0.68)	$ (0.86)
Basic and diluted-pro forma	$ (0.88)	$ (0.74)	$ (0.91)

Comprehensive Income

In accordance with Statement of Financial Accounting Standard No. 130, "Reporting Comprehensive Income" (SFAS 130), the Company has reported comprehensive income, defined as net income (loss) plus other comprehensive income, in the Statements of Stockholders' Equity. The total of other accumulated comprehensive income consists of unrealized gains and losses on marketable securities.

Per Share Data

Basic earnings per share ("EPS") is based on the weighted average number of common shares outstanding. Diluted EPS is based on the weighted average number of common shares and dilutive potential common shares. Dilutive potential common shares are calculated under the treasury stock method and consist of unexercised stock options and warrants.

Use of Estimates

The preparation of financial statement in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Recent Accounting Pronouncements

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

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

1. A "modified prospective" method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123R for all

share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of SFAS 123R that remain unvested on the effective date, or

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

As permitted by SFAS 123, we currently account for share-based payments to employees using APB Opinion 25's intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. The impact of the adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, valuation of employee stock options under SFAS 123R is similar to SFAS 123, with minor exceptions. For information about what our reported results of operations and earnings per share would have been had we adopted SFAS 123, please see the discussion under the heading "Stock Based Compensation" in Note 1 to our Financial Statements. Accordingly, the adoption of SFAS 123R's fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. Due to timing of the release of SFAS 123R, we have not yet completed the analysis of the ultimate impact that this new pronouncement will have on the results of operations, nor the method of adoption for this new standard.

Reclassifications

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

2. Marketable Securities

Marketable securities consist of the following at December 31, 2004 and 2003:

	Cost	Unrealized Gains	Unrealized Losses	Fair Value
2004:				
Corporate debt securities (principally commercial paper and bonds/notes) and government securities	$ 20,198,284	$ —	$ (34,643)	$ 20,163,641

	Cost	Unrealized Gains	Unrealized Losses	Fair Value
2003:				
Corporate debt securities (principally commercial paper) and government securities	$ 17,950,430	$ 4,161	$ (13)	$ 17,954,578

Realized gains on the sales of available-for-sale securities were $1,058, $1,893 and $10,191 in 2004, 2003 and 2002, respectively. The realized losses on sales of available for sale securities were $0, $0 and $6,869 in 2004, 2003 and 2002, respectively. All marketable securities at December 31, 2004 mature within one year.

3. Equipment, Furniture and Leasehold Improvements

Equipment, furniture and leasehold improvements consist of the following:

	2004	2003
Laboratory equipment	$ 3,613,803	$ 3,671,095
Construction in progress	—	1,073
Office furniture and equipment	1,183,541	1,012,633
Leasehold improvements	1,304,487	1,260,315
	6,101,831	5,945,116
Less accumulated depreciation and amortization	4,622,046	4,339,055
	$ 1,479,785	$ 1,606,061

We held laboratory equipment acquired under capital leases with an original cost of $392,968 as of December 31, 2004 and 2003. Accumulated depreciation on this equipment was $300,900 and $186,507 at December 31, 2004 and 2003, respectively.

4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following:

	2004	2003
Clinical trials	$ 912,643	$ 446,001
Accrued compensation	792,755	731,858
Accounts payable	815,203	196,878
Accrued legal & professional	423,732	42,600
Other	232,376	225,610
	$ 3,176,709	$ 1,642,947

5. Income Tax

Income tax benefit consists of the following:

	2004	2003	2002
Federal – current	$ —	$ —	$ 101,483

The Company recorded no income tax expense or benefit during 2004 or 2003. During 2002, the Company recognized an income tax benefit of $101,000 related to changes in federal tax regulations for the treatment of net operating losses for alternative minimum taxes that were originally paid in 1996, 1997 and 1999. This change in regulations occurred in early 2002 and the Company subsequently filed amended returns and received the refunds in late 2002.

A reconciliation of the Federal Statutory tax rate of 34% to the Company's effective income tax rate follows:

	2004	2003	2002
Statutory tax rate	(34.00)%	(34.00)%	(34.00)%
Permanent difference	0.05	0.02	0.17
Change in valuation allowance	33.95	33.98	33.83
AMT refunds	—	—	(0.86)
Effective tax rate	0.0%	0.0%	(0.86)%

Significant components of the Company's net deferred tax assets and liabilities as of December 31, 2004 and 2003 are as follows:

	2004	2003
Deferred tax assets:		
Federal net operating loss carryforwards	$ 22,698,000	$ 17,273,000
Accrued expenses	192,000	187,000
Research and development credits	2,299,000	2,103,000
Foreign tax credits	—	1,029,000
Book in excess of tax depreciation expense	69,000	142,000
Gross deferred tax assets	25,258,000	20,734,000
Valuation allowance for net deferred tax assets	(25,258,000)	(20,734,000)
Net deferred tax assets	$ —	$ —

Due to the uncertainty of the Company's ability to generate taxable income to realize its net deferred tax assets at December 31, 2004 and 2003, a valuation allowance has been recognized for financial reporting purposes. The Company's valuation allowance for deferred tax assets increased $4.5 million and $3.9 million for the years ended December 31, 2004 and 2003, respectively. The increase in the deferred tax assets in 2004 is primarily the result of increasing net operating loss carryforwards.

At December 31, 2004, the Company has federal net operating loss carryforwards of approximately $66.8 million for income tax reporting purposes and research and development tax credit carryforwards of approximately $2.3 million. The federal operating loss carryforwards and research and development credits begin to expire in 2006. Approximately $1.0 million in foreign tax credits expired in 2004. To the extent that net operating loss carryforwards, when realized, relate to stock option deductions of approximately $2.5 million, the resulting benefit will be credited to stockholders' equity.

The initial public offering of common stock by the Company in 1995 caused an ownership change pursuant to applicable regulations in effect under the Internal Revenue Code of 1986. Therefore, the Company's use of losses incurred through the date of ownership change will be limited during the carryforward period and may result in the expiration of net operating loss carryforwards before utilization.

6. Stockholders' Equity

Common Stock

At December 31, 2004, the Company had shares of common stock reserved for possible future issuance as follows:

Stock options outstanding	3,010,509
Warrants outstanding	1,828,116
Shares available for future grant under stock plans	1,383,295
	6,221,920

Private Placements

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

In July 2003, the Company sold 3.9 million shares of common stock and warrants to purchase 1.95 million shares of common stock in a private placement transaction for gross proceeds of $14.2 million ($13.2 million net of transaction costs). The common stock and warrants were sold at a total price of $3.62 per share. The warrants are exercisable at $4.09 per share and expire in July 2008.

Stock Warrants

At December 31, 2004, there were warrants outstanding to purchase 1.8 million shares of common stock at exercise prices ranging from $4.09 to $9.40 per share. During 2004, the Company recorded $1.4 million in proceeds from the issuance of 345,000 shares of common stock from the exercise of common stock warrants. During 2003, the Company recorded $729,000 in proceeds from the issuance of 237,000 shares of common stock from the exercise of common stock warrants.

Stock Options

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.

A summary of activity related to the Company's stock options follows:

	Shares	Exercise Price
Balance, December 31, 2001	2,537,272	.20 — 44.00
Granted	556,571	1.46 — 7.35
Exercised	(74,508)	.88 — 6.06

Canceled	(800,541)	4.00 — 38.63
Balance, December 31, 2002	2,218,794	.20 — 44.00
Granted	817,827	2.14 — 5.08
Exercised	(78,220)	.20 — 3.79
Canceled	(369,749)	1.46 — 44.00
Balance, December 31, 2003	2,588,652	.63 — 44.00
Granted	926,575	2.86 — 7.84
Exercised	(136,670)	.63 — 3.38
Canceled	(368,048)	.88 — 8.08
Balance, December 31, 2004	3,010,509	.63 — 44.00

Options exercisable at December 31, 2004, 2003, and 2002, were 1,485,380; 1,346,995 and 1,260,020, respectively. The weighted average exercise prices for those options for the years ended December 31, 2004, 2003 and 2002, were $4.13, $4.23 and $2.67, respectively

The following table summarizes information about stock options outstanding at December 31, 2004:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.63 - $1.46	268,600	5.82 years	$ 0.74	267,166	$ 0.75
$2.03 - $3.65	1,057,507	9.01 years	$ 2.80	279,042	$ 2.21
$3.72 - $6.00	954,656	8.55 years	$ 5.65	457,329	$ 5.38
$6.25 - $8.19	702,113	6.44 years	$ 7.04	454,210	$ 7.15
$19.38 - $20.50	15,000	2.80 years	$ 19.75	15,000	$ 19.75
$37.00 - $44.00	12,633	2.88 years	$ 39.77	12,633	$ 39.77
Total	3,010,509	7.72 years	$ 4.54	1,485,380	$ 4.98

Pro forma information regarding net loss per share required by SFAS 123 and disclosed in Note 1 has been determined as if we accounted for our employee options under the fair value method of SFAS 123. The fair value of each option is estimated using the Black-Scholes option pricing model. The assumptions used in this model include (1) the stock price at grant date, (2) the exercise price, (3) an estimated option life of four years (4) no expected dividends for each year presented, (5) stock price volatility factor of .9913, 1.116, and 1.154 in 2004, 2003 and 2002, respectively, and (6) a risk-free interest rate of 3.49%, 2.97% and 3.82% in 2004, 2003 and 2002, respectively. The weighted average fair value per share of options granted during 2004, 2003 and 2002 was $2.89, $3.17 and $2.06, respectively.

Stock Purchase Plan

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 three-month offering period. Shares purchased under the plan were 3,390, 10,860 and 19,002 in 2004, 2003 and 2002, respectively. At December 31, 2004, a total of 12,550 shares remain available for future purchases by employees under the plan.

401(k) Plan

The Company has a 401(k) plan for all employees under which it provides a specified percentage match on employee contributions. Currently, the Company match is made in shares of the Company's common stock. Shares issued as matching contributions under the plan were 10,568; 9,645 and 18,240 in 2004, 2003 and 2002, respectively. The related expense recorded on these matching contributions was $44,400, $33,400 and $42,900 in 2004, 2003 and 2002, respectively. At December 31, 2004, a total of 47,069 shares remain available for future issuances as matching contributions under the plan.

Shareholder Rights Plan

The Company has adopted a Shareholder Rights Plan ("Plan") which was amended in July 2002. Under the Plan, as amended, the Company's Board of Directors declared a dividend of one Preferred Stock Purchase Right ("Right") for each outstanding common share of the Company. The Rights have an exercise price of $140 per Right and provide the holders with the right to purchase, in the event a person or group acquires 15% or more of the Company's common stock, additional shares of the Company's common stock having a market value equal to two times the exercise price of the Right. The Rights expire in 2006.

7. Net Income (Loss) Per Share

A reconciliation between basic and diluted net loss per share is as follows:

	2004	2003	2002
Basic net loss per share:			
Net loss	$ (16,310,592)	$ (10,467,099)	$ (11,635,801)
Weighted average common shares	20,169,258	15,503,794	13,563,754
Basic net loss per share	$ (0.81)	$ (0.68)	$ (0.86)
Diluted net loss per share:			
Net loss	$ (16,310,592)	$ (10,467,099)	$ (11,635,801)
Weighted average common shares	20,169,258	15,503,794	13,563,754
Dilutive potential common shares	—	—	—
Total dilutive shares	20,169,258	15,503,794	13,563,754
Diluted net loss per share	$ (0.81)	$ (0.68)	$ (0.86)

As of December 31, 2004, 2003 and 2002 a total of 4,838,625; 4,761,483 and 2,779,094 options and warrants, respectively, have not been included in the calculation of

potential common shares as their effect on diluted per share amounts would have been anti-dilutive.

8. Commitments and Contingencies

The Company has leased office space and equipment under two operating lease agreements, which expire in July 2007 and November 2007, respectively. Under the office space lease, the Company has the option to extend the lease for an additional three years at the then fair market value of the leased premises. Future minimum lease payments under these leases are as follows:

2005	$ 686,928
2006	701,928
2007	426,808
2008	0
2009	0
	$ 1,815,664

Rental expense for the years ended December 31, 2004, 2003 and 2002 was $647,000, $553,000 and $528,000, respectively.

The Company also entered into two capital leases for laboratory equipment and a leasehold financing arrangement in 2002. Both capital leases have terms of 36 months, implied interest rates of approximately 10% and are secured by the underlying assets. The leasehold financing arrangement has a term of 64 months and an interest rate of 10%. The following is a summary of the lease obligations and the related future minimum payments as of December 31, 2004:

2005	$ 85,279
2006	30,392
2007	15,197
2008	0
2009	0
Total lease payments	130,868
Less amount representing interest	(10,251)
Present value of net minimum lease payments	120,617
Less current portion	78,445
Long-term lease obligations, excluding current portion	$ 42,172

9. Quarterly Financial Information (unaudited)

	Quarter Ended			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
2004				
Revenue	$ —	$ —	$ —	$ —
Operating expenses	$ 3,614	$ 3,817	$ 3,692	$ 5,453
Operating loss	$ (3,614)	$ (3,817)	$ (3,692)	$ (5,453)
Net loss	$ (3,578)	$ (3,761)	$ (3,612)	$ (5,360)
Net loss per share:				
Basic	$ (0.20)	$ (0.19)	$ (0.17)	$ (0.25)
Diluted	$ (0.20)	$ (0.19)	$ (0.17)	$ (0.25)
2003				
Revenue	$ 25	$ —	$ —	$ —
Operating expenses	$ 2,359	$ 3,116	$ 2,540	$ 2,648
Operating loss	$ (2,334)	$ (3,116)	$ (2,540)	$ (2,648)
Net loss	$ (2,274)	$ (3,086)	$ (2,501)	$ (2,606)
Net loss per share:				
Basic	$ (0.17)	$ (0.22)	$ (0.15)	$ (0.14)
Diluted	$ (0.17)	$ (0.22)	$ (0.15)	$ (0.14)

10. Subsequent Event: Termination of Material Definitive Agreement

On December 22, 2004, we executed an Amended and Restated Stock Purchase Agreement with the stockholders of Synt:em S.A. for the purchase of all of the outstanding capital stock of Synt:em. On March 15, 2005, we delivered an irrevocable notice to the Chief Executive Officer of Synt:em, S.A., pursuant to Sections 8.1(e) and 8.2 the Amended and Restated Stock Purchase Agreement terminating the Amended and Restated Stock Purchase Agreement effective March 31, 2005.

In reaching our conclusion to terminate the Amended and Restated Stock Purchase Agreement, management weighed the increased human and financial resources required to take advantage of opportunities with TOCOSOL® Paclitaxel, our lead oncology candidate, against the human and financial resources required to complete the transaction and subsequent integration of the Synt:em S.A. business with our business. We concluded that the best course of action was to focus our resources on opportunities with TOCOSOL® Paclitaxel and remain as a standalone company.

According to the terms of the Amended and Restated Stock Purchase Agreement, properly terminating the Amended and Restated Stock Purchase Agreement pursuant to Section 8.1(e) will not result in any material early termination penalties or financial liability to us. Through December 31, 2004, we incurred approximately $1.0 million in legal, accounting and investment banker fees on this transaction. These charges are reflected in our 2004 financial statements as general and administrative expense. We anticipate that we will incur an additional $100,000 to $200,000 in legal, accounting and investment banker fees in 2005 for work done subsequent to December 31, 2004.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")), as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

In addition, no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) occurred during the fourth quarter of our fiscal year ended December 31, 2004 that has materially affected, or is reasonable likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

The management of Sonus Pharmaceuticals, Inc. (the "Company") is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a–15(f) under the Securities Exchange Act of 1934. The Company's internal control over financial reporting is a process designed under the supervision of the Company's principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2004, management assessed the effectiveness of the Company's internal control over financial reporting based on the framework established in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this evaluation, management has determined that the Company's internal control over financial reporting was effective as of December 31, 2004.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management's assessment of the effectiveness of its internal control over financial reporting as of December 31, 2004, has been audited by Ernst &Young LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders of Sonus Pharmaceuticals, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Sonus Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Sonus Pharmaceutical Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Sonus Pharmaceuticals, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Sonus Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Sonus Pharmaceuticals, Inc. as of December 31, 2004 and 2003, and the related statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2004 of Sonus Pharmaceuticals, Inc. and our report dated March 16, 2005 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP

Seattle, Washington
March 16, 2005

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

In compliance with Section 406 of the Sarbanes-Oxley Act of 2002 and the Nasdaq corporate governance listing standards, the Company has adopted a code of conduct that is applicable to all of the Company's employees and directors. Interested parties may request a copy of this code of conduct, free of charge, by delivering a written request addressed to the Chief Financial Officer, Sonus Pharmaceuticals, Inc., 22026 20th Avenue S.E., Bothell, Washington 98021. The Company will disclose any amendments to the code of conduct and any waivers from the code of conduct for directors and executive officers by posting such information on its website at www.sonuspharma.com.

The other information required hereunder is incorporated by reference from our Proxy Statement to be filed in connection with its 2005 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required hereunder is incorporated by reference from our Proxy Statement to be filed in connection with its 2005 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding our equity compensation plans as of December 31, 2004:

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)
Equity compensation plans approved by security holders (1)	2,503,240	$ 4.50	1,310,948
Equity compensation plans not approved by security holders (2)	507,269	$ 4.78	25,278
Total	3,010,509		1,336,226

(1) Our 2000 Stock Incentive Plan was approved by security holders with 500,000 shares authorized under the plan. Stock options issued under the 2000 plan are generally granted at the fair market value on the date of grant and expire ten years from the date of grant. The plan also has an annual feature whereby 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. 1,298,398 shares were available for issuance as of December 31, 2004. The Company also had 12,550 shares available at December 31, 2004 for issuance under its Employee Stock Purchase Plan.

(2) Our 1999 Nonqualified Stock Incentive Plan (the "1999 Plan") is a broad-based plan for which shareholder approval was not required or obtained. A total of 900,000 shares are authorized under the 1999 Plan with 25,278 available for issuance as of December 31, 2004. Options to purchase 507,269 shares of common stock under the 1999 Plan were outstanding as of December 31, 2004 at a weighted average exercise price of $4.78. Stock options issued under the 1999 Plan are generally granted with an exercise price equal to fair market value on the date of grant, but in no event may be less than 85% of the then fair market value. Options under the 1999 Plan have various vesting schedules and expire ten years from the date of grant. The 1999 Plan also authorizes the issuance of restricted stock, although no restricted stock grants have been issued under the 1999 Plan. Shares underlying unexercised options that expire or are terminated become available again for future grants.

The remaining information required hereunder is incorporated by reference from our Proxy Statement to be filed in connection with its 2005 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required hereunder is incorporated by reference from our Proxy Statement to be filed in connection with its 2005 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required hereunder is incorporated by reference from our Proxy Statement to be filed in connection with its 2005 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) (1) Financial Statements

Report of Independent Registered Public Accounting Firm

Balance Sheets as of December 31, 2004 and 2003

Statements of Operations for the years ended December 31, 2004, 2003, and 2002

Statements of Stockholders' Equity for the years ended December 31, 2004, 2003, and 2002

Statements of Cash Flows for the years ended December 31, 2004, 2003, and 2002

Notes to the Financial Statements

(2) All schedules are omitted because they are not required or the required information is included in the financial statements or notes thereto.

(3) Exhibits

Index to Exhibits

Exhibit No.	Description	Location
Exhibit No. 2: Plan of Acquisition		
2.1	Stock Purchase Agreement, dated November 3, 2004	(22)
2.2	Amended and Restated Stock Purchase Agreement, dated December 22, 2004.	(23)
Exhibit No. 3: Articles of Incorporation		
3.2	Amended and Restated Certificate of Incorporation of the Company.	(1)
3.3	Certificate of Amendment of Certificate of Incorporation of the Company.	(7)
3.4	Amended and Restated Bylaws of the Company.	(1)
3.5	Amended and Restated Certificate of Incorporation of the Company.	(19)
Exhibit No. 4: Instruments Defining the Rights of Security Holders		
4.1	Specimen Certificate of Common Stock.	(1)
4.2	Rights Agreement, dated as of August 23, 1996, between the Company and U.S. Stock Transfer Corporation.	(3)
4.3	First Amendment to Rights Agreement, dated as of August 23, 1996, between the Company and U.S. Stock Transfer Corporation.	(17)

Index to Exhibits

Exhibit No.	Description	Location
Exhibit No. 10: Material Contracts		
Compensation Plans and Arrangements		
10.1	Sonus Pharmaceuticals, Inc. Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan – 1991 (the "1991 Plan"), as amended.	(1)
10.2	Form of Incentive Stock Option Agreement pertaining to the 1991 Plan.	(1)
10.3	Form of Nonqualified Stock Option Agreement pertaining to the 1991 Plan.	(1)
10.4	Form of Restricted Stock Purchase Agreement pertaining to the 1991 Plan.	(1)
10.5	Sonus Pharmaceuticals, Inc. 1995 Stock Option Plan for Directors (the "Director Plan").	(1)
10.6	Form of Stock Option Agreement pertaining to the Director Plan.	(1)
10.7	1999 Nonqualified Stock Incentive Plan (the "1999 Plan").	(7)
10.8	Form of Stock Option Agreement pertaining to the 1999 Plan.	(7)
10.9	Form of Restricted Stock Purchase Agreement pertaining to the 1999 Plan.	(7)
10.10	2000 Stock Incentive Plan (the "2000 Plan").	(9)
10.11	Form of Stock Option Agreement pertaining to the 2000 Plan.	(9)
10.12	Sonus Pharmaceuticals, Inc. Employee Stock Purchase Plan.	(2)
10.13	Change in Control Agreement for Michael Martino, dated September 15, 1998.	(4)
10.14	Change in Control Agreement for Richard J. Klein, dated October 25, 2000.	(10)
10.15	Change in Control Agreement for Michael A. Martino, dated July 18, 2001.	(12)
10.16	Change in Control Agreement for Michael B. Stewart, dated May 1, 2003.	(18)
10.17	Change in Control Agreement for Michael A. Martino, dated October 10, 2003.	(6)
10.18	Change in Control Agreement for Richard J. Klein, dated October 10, 2003.	(6)
10.19	Change in Control Agreement for Michael B. Stewart, dated October 10, 2003.	(6)
10.20	Change in Control Agreement for Alan Fuhrman, dated September 15, 2004.	(21)
10.21	Amended and Restated Executive Compensation Program.	(24)
10.22	Form of Performance Award under Executive Compensation Program.	(24)
Other Material Contracts		
10.20	Lease Agreement dated January 17, 1994 between the Company and WRC Properties, Inc.	(1)
10.21	Amendment 2 dated October 28, 1997 to Lease Agreement dated January 17, 1994.	(5)
10.22	Amendment 3 dated October 15, 1998 to Lease Agreement dated January 17, 1994.	(5)
10.23	Amendment 4 dated November 29, 2001 to Lease Agreement dated January 17, 1994.	(15)
10.24	Form of Indemnification Agreement for Officers and Directors of the Company.	(1)
10.25	License Agreement by and between Nycomed Amersham AS and the Company dated August 31, 1999.	(8)
10.26	License Agreement by and between Chugai Pharmaceutical Co. Ltd., Molecular Biosystems, Inc., and the Company, dated December 22, 2000.	(11)
10.27	Nycomed Assignment and Asset Transfer Agreement, dated August 3, 2001.	(13)
10.28	Supply Agreement dated January 22, 2002 between Indena SpA and Sonus Pharmaceuticals, Inc.	(14)
10.29	First Amendment dated May 5, 2003 to Supply Agreement dated January 22, 2002 between Indena SpA and Sonus Pharmaceuticals, Inc.	(18)
10.30	Manufacturing and Supply Agreement by and between the Company and Gensia Sicor Pharmaceutical Sales, Inc., dated June 26, 2002.	(16)
10.31	Securities Purchase Agreement, dated May 7, 2004.	(20)
10.32	Registration Rights Agreement, dated May 7, 2004.	(20)

Index to Exhibits

Exhibit No.	Description	Location
Exhibit No. 23: Consents of Experts and Counsel		
23.1	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.	(6)
24.1	Power of Attorney (included on the Signature Page of this Annual Report on Form 10-K).	(6)

Certifications		
31.1	Certification of President and Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a).	(6)
31.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a).	(6)
32.1	Certification of President and Chief Executive Officer pursuant to Rule 13a-14(b) or 15d-14(b).	(6)
32.2	Certification of the Chief Financial Officer pursuant to Rule 13a-14(b) or 15d-14(b).	(6)

(1) Incorporated by reference to the Company's Registration Statement on Form S-1, Reg. No. 33-96112.

(2) Incorporated by reference to the Company's Registration Statement on Form S-1, Reg. No. 33-80623.

(3) Incorporated by reference to the Company's Registration Statement on Form 8-A, dated August 23, 1996.

(4) Incorporated by, reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 1998.

(5) Incorporated by reference to the Company's Annual Report on Form 10-K for the period ended December 31, 1998.

(6) Filed herewith.

(7) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 1999.

(8) Incorporated by reference to the Company's Current Report on Form 8-K dated September 28, 1999.

(9) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2000.

(10) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2000.

(11) Incorporated by reference to the Company's Annual Report on Form 10-KA for the period ended December 31, 2000.

(12) Incorporated by reference to the Company's Quarterly Report on Form 10-QA for the quarterly period ended June 30, 2001.

(13) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2001.

(14) Incorporated by reference to the Company's Registration Statement on Form S-3 filed February 8, 2002.

(15) Incorporated by reference to the Company's Annual Report on Form 10-K for the period ended December 31, 2001.

(16) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2002.

(17) Incorporated by reference to the Company's filing on Form 8-A12G/A dated July 25, 2002.

(18) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2003.

(19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2004.

(20) Incorporated by reference to the Company's Current Report on Form 8-K filed May 13, 2004.

(21) Incorporated by reference to the Company's Current Report on Form 8-K filed September 20, 2004.

(22) Incorporated by reference to the Company's Current Report on Form 8-K filed November 8, 2004.

(23) Incorporated by reference to the Company's Current Report on Form 8-K filed December 28, 2004.

(24) Incorporated by reference to the Company's Current Report on Form 8-K filed January 4, 2005.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized, in the City of Bothell, State of Washington, on March 12, 2004.

SONUS PHARMACEUTICALS, INC.

Dated: March 23, 2005

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

We, the undersigned directors and officers of Sonus Pharmaceuticals, Inc., do hereby constitute and appoint Michael A. Martino and Alan Fuhrman, or either of them, our true and lawful attorneys and agents, with full powers of substitution to do any and all acts and things in our name and on behalf in our capacities as directors and officers and to execute any and all instruments for us and in our names in the capacities indicated below, which said attorneys and agents may deem necessary or advisable to enable said corporation to comply with the Securities Exchange Act of 1934, as amended, and any rules, regulations and requirements of the Securities and Exchange Commission, in connection with this Annual Report on Form 10-K, including specifically but without limitation, power and authority to sign for us or any of us in our names in the capacities indicated below, any and all amendments thereto; and we do hereby ratify and confirm all that said attorneys and agents, shall do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the

capacities and on the dates indicated.

/s/ Michael A. Martino Michael A. Martino	President, Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2005
/s/ Alan Fuhrman Alan Fuhrman	Senior Vice President, Chief Financial Officer (Principal Financial Officer)	March 23, 2005
/s/ Craig S. Eudy Craig S. Eudy	Vice President, Corporate Controller (Principal Accounting Officer)	March 23, 2005
/s/ Michelle Burris Michelle Burris	Director	March 23, 2005
/s/ George W. Dunbar, Jr. George W. Dunbar, Jr.	Director, Co-Chairman of the Board of Directors	March 23, 2005
/s/ Robert E. Ivy Robert E. Ivy	Director, Co-Chairman of the Board of Directors	March 23, 2005
/s/ Dwight Winstead Dwight Winstead	Director	March 23, 2005

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-8 No. 333-80623, No. 333-36093, No. 333-56933, No. 333-87897, No. 333-49892, and No. 333-56704) pertaining to the Sonus Pharmaceuticals, Inc., Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan-1991, 1995 Stock Option Plan for Directors, Employee Stock Purchase Plan, 1999 Nonqualified Stock Incentive Plan, 2000 Stock Incentive Plan and 401(k) Profit Sharing Plan and Trust and in the Registration Statements (Form S-3 No. 333-115876, No. 333-64966, No. 333-82414 and No. 333-107987) pertaining to the registration for resale of shares of common stock of Sonus Pharmaceuticals, Inc. and in the related Prospectuses of our reports dated March 16, 2005, with respect to the financial statements of Sonus Pharmaceuticals, Inc., Sonus Pharmaceuticals, Inc. management's assessment of the effectiveness of internal control over financial reporting, and the effectiveness of internal control over financial reporting of Sonus Pharmaceuticals, Inc., included in this Annual Report (Form 10-K) for the year ended December 31, 2004.

Seattle, Washington
March 22, 2005

EXHIBIT 31.1

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, Michael A. Martino, certify that:

1. I have reviewed this annual report on Form 10-K 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: March 23, 2005

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

EXHIBIT 31.2

Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934

I, Alan Fuhrman, certify that:

1. I have reviewed this annual report on Form 10-K 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: March 23, 2005

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

EXHIBIT 32.1

Certification Pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and U.S.C. Section 1350

I, Michael A. Martino, President and Chief Executive Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2004 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2005

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

EXHIBIT 32.2

Certification Pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and U.S.C. Section 1350

I, Alan Fuhrman, Senior Vice President and Chief Financial Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that:

(1) the Annual Report on Form 10-K of the Company for the annual period ended December 31, 2004 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 23, 2005

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