U.S. SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-Q

X	QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD	
	C	or
	TRANSITION REPORT PURSUANT TO SECTION 13 OR 150 EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD	
	Commission file	number 0-26866
	Sonus Pharma	aceuticals, Inc.
	(Exact Name of Registrant	as Specified in Its Charter)
	Delaware (State or Other Jurisdiction of Incorporation or Organization)	95-4343413 (I.R.S. Employer Identification Number)
		thell, Washington 98021 al Executive Offices)
		87-9500 mber, Including Area Code)
		on 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months as been subject to such filing requirements for the past 90 days. Yes X No
State the number of	of shares outstanding of each of the issuer's classes of common equity	as of the latest practicable date.
	Class	Outstanding at August 6, 2002
	Common Stock, \$.001 par value	13,661,483
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Items 1, 2, 3 and 5 are not applicable and have been omitted.

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Part I. Financial Information

Item 1. Financial Statements

Sonus Pharmaceuticals, Inc. Balance Sheets

	June 30, 2002	December 31, 2001
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	\$ 22,107,593	\$ 15,123,914
Other current assets	397,370	343,057
Total current assets	22,504,963	15,466,971
Equipment, furniture and leasehold improvements, net of accumulated depreciation of \$3,862,268 and \$3,698,552	1,295,511	396,711
Total assets	\$ 23,800,474	\$ 15,863,682
Liabilities and Stockholders' Equity Current liabilities:		
Accounts payable and accrued expenses	\$ 2,083,756	\$ 1,198,552
Current portion of lease obligations	74,758	_
m . 1 W 1999	2.150.514	1 100 550
Total current liabilities	2,158,514	1,198,552
Lease obligations, less current portion Commitments and contingencies	274,394	_
Stockholders' equity:		
Preferred stock; \$.001 par value; 5,000,000 authorized; no shares issued or outstanding Common stock; \$.001 par value; 30,000,000 shares authorized; 13,658,283 and 11,650,797	_	_
shares issued and outstanding at June 30, 2002 and December 31, 2001, respectively	55,985,505	43,302,286
Accumulated deficit	(34,634,139)	(28,676,864)
Accumulated other comprehensive income (loss)	16,200	39,708
Total stockholders' equity	21,367,566	14,665,130
Total liabilities and stockholders' equity	\$ 23,800,474	\$ 15,863,682

See accompanying notes.

Sonus Pharmaceuticals, Inc. Statements of Operations (Unaudited)

Three Months Ended June 30, Six Months Ended June 30,

	2002	2001	2002	2001
Revenues	\$ —	\$ 91,188	\$ 25,000	\$ 1,186,716
Operating expenses:				
Research and development	2,832,678	1,325,132	4,514,021	2,493,193
General and administrative	861,149	615,824	1,726,288	1,312,540
Total operating expenses	3,693,827	1,940,956	6,240,309	3,805,733
Operating loss	(3,693,827)	(1,849,768)	(6,215,309)	(2,619,017)
Interest income (expense):				
Interest income	157,072	110,197	265,914	252,081
Interest expense	(6,836)	(3,650)	(7,880)	(13,858)
Total interest income, net	150,236	106,547	258,034	238,223
Loss before taxes	(3,543,591)	(1,743,221)	(5,957,275)	(2,380,794)
Γaxes			`´ <u> </u>	100,000
Net loss	\$ (3,543,591)	\$(1,743,221)	\$ (5,957,275)	\$(2,480,794)
Basic and diluted net loss per share	\$ (0.26)	\$ (0.18)	\$ (0.44)	\$ (0.27)
Shares used in computation of basic and diluted net loss	` ′	`	`	`
per share	13,649,379	9,507,221	13,456,693	9,355,069

See accompanying notes.

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

Civ	Mont	o En	dod I	me 30.

	2002	2001
Operating activities:		
let loss	\$ (5,957,275)	\$ (2,480,791)
adjustments to reconcile net loss to net cash used in operating activities:	` ' '	
Depreciation	163,716	154,348
Amortization of net premium (discount) on marketable securities	142,754	10,111
Realized losses on marketable securities	676	_
Noncash stock compensation expense	_	50,214
Changes in operating assets and liabilities:		
Other current assets	(54,313)	(69,990)
Accounts payable and accrued expenses	885,204	1,447,401
et cash used in operating activities	(4,819,238)	(888,707)
envesting activities:		
urchases of capital equipment and leasehold improvements	(1,062,516)	(24,507)
urchases of marketable securities	(18,491,874)	(6,973,789)
roceeds from sales of marketable securities	3,831,968	1,735,320
roceeds from maturities of marketable securities	7,372,000	4,700,681
et cash used in investing activities	(8,350,422)	(562,295)
inancing activities:		
roceeds from lease obligations	366,885	_
ayments on lease obligations	(17,733)	_
roceeds from bank line of credit		5,000,000
epayment of bank line of credit	_	(10,000,000)
roceeds from issuance of common stock	12,683,219	4,462,582
occess from issuance of common stock	12,005,217	4,402,302
let cash provided by (used in) investing activities	13,032,371	(537,418)
et cash provided by (used in) hivesting activities	13,032,371	(337,418)
1 ' 1 1 ' 1 (C 4 ' 1	(127.200)	(1,000,400)
hange in cash and cash equivalents for the period	(137,289)	(1,988,420)
ash and cash equivalents at beginning of period	455,073	6,696,610
ash and cash equivalents at end of period	317,784	4,708,190
farketable securities at end of period	21,789,809	7,301,704
otal cash, cash equivalents and marketable securities	\$ 22,107,593	\$ 12,009,894
upplemental cash flow information:		
Interest paid	\$ 7,880	\$ 18,958
Income taxes paid	\$ 7,860 \$ —	\$ 100,000
meome and paid	ψ	φ 100,000

See accompanying notes.

Sonus Pharmaceuticals, Inc. Notes to Financial Statements (Unaudited)

1. Basis of Presentation

The unaudited financial statements have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all of the information and footnotes required to be presented for complete financial statements. The accompanying financial statements reflect all adjustments (consisting only of normal recurring items) which are, in the opinion of management, necessary for a fair presentation of the results for the interim periods presented.

The financial statements and related disclosures have been prepared with the assumption that users of the interim financial information have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these financial statements should be read in conjunction with the audited financial statements and the related notes thereto included in the Form 10-K for the year ended December 31, 2001 and filed with the Securities and Exchange Commission on March 5, 2002.

2. Comprehensive Income (Loss)

	Three months ended June 30,		Six months ended June 30,	
	2002	2001	2002	2001
Net Income (loss)	\$(3,543,591)	\$(1,743,221)	\$(5,957,275)	\$(2,480,794)
Unrealized gain (loss) on marketable securities	47,894	1,189	(23,508)	9,173
Comprehensive income (loss)	\$(3,495,697)	\$(1,742,032)	\$(5,980,783)	\$(2,471,621)

3. Common Stock

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

4. Cash, Cash Equivalents and Marketable Securities

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

	June 30, 2002	December 31, 2001
Cash and cash equivalents Marketable securities	\$ 317,784 21,789,809	\$ 455,073 14,668,841
	\$22,107,593	\$15,123,914
	\$22,107,373	\$13,123,711

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

Forward-Looking Statements

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

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

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

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

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

Certain of these risk factors are discussed in more detail in our Annual Report on Form 10-K for the year ended December 31, 2001.

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

The Company is applying its expertise in drug delivery to make therapeutic drugs safer, easier to administer and more effective. The Company's TOCOSOL™ drug delivery technology, a Vitamin E based oil-in-water emulsion, is broadly applicable to multiple drugs, diseases and dosage forms. We currently have a cancer therapy product, TOCOSOL Paclitaxel (formerly known as S-8184), in Phase 2 clinical trials, and we also have several active compounds under investigation in therapeutic areas that target cancer, cardiovascular disease, diabetes and infection. We plan to file an Investigational New Drug Application (IND) on one of these compounds in late 2002.

The Company's first application of its TOCOSOL drug delivery technology is an injectable paclitaxel emulsion formulation, TOCOSOL Paclitaxel. Paclitaxel is the active ingredient in the world's leading cancer drug, Taxol® (the Bristol-Myers Squibb product), which is approved in the U.S. for the treatment of breast, ovarian and non-small cell lung tumors. We filed an Investigational New Drug Application, or IND, for TOCOSOL Paclitaxel with the U.S. Food and Drug Administration (FDA) in September 2000 and initiated a Phase 1 human clinical study in December 2000. The Company has completed the Phase 1 study and TOCOSOL Paclitaxel is currently being studied in four Phase 2 studies to evaluate efficacy in non-small cell lung, ovarian, bladder and colorectal cancers.

The Company completed its Phase 1 study in May 2002 after enrolling a total of 37 patients. The objectives of the Phase 1 study were to determine the maximum tolerated dose of TOCOSOL Paclitaxel and to evaluate safety. Preliminary Phase 1 results suggest that TOCOSOL Paclitaxel may provide safety and convenience advantages for both patients and physicians including a reduction in side effects, steroid premedications and administration time using a ready-to-use formulation in a single, quick injection administered in less than 15 minutes compared to the three-hour infusion of existing formulations of paclitaxel. Based on preclinical and clinical studies, we also believe there may be potential efficacy benefits of TOCOSOL Paclitaxel that may result from higher concentrations of the drug delivered to the tumor and higher sustained dose density within the tumor. In Phase 1 tests measuring levels of paclitaxel in blood, a quick injection of TOCOSOL Paclitaxel resulted in higher peak drug concentrations, higher total drug exposure and slower clearance times compared with published literature for a three-hour infusion of Taxol.

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

Phase 2 studies for TOCOSOL Paclitaxel were initiated in March of 2002. The Phase 2 program is designed to evaluate the efficacy of TOCOSOL Paclitaxel in specific tumor types. Our goal is to obtain

a clear measure of efficacy with TOCOSOL Paclitaxel and to quickly determine the indications where the product shows the greatest efficacy. The first four Phase 2 studies will evaluate TOCOSOL Paclitaxel in non-small cell lung, ovarian, bladder and colorectal cancers using weekly dosing of TOCOSOL Paclitaxel. Each Phase 2 study will begin with a dose escalation phase to determine the MTD of TOCOSOL Paclitaxel. Weekly dose levels to be studied include 80, 100 and 120 mg/m². The MTD will be determined separately for each of the four studies. These will be single agent, second line studies enrolling patients that have not previously had taxane chemotherapy treatments. Initial efficacy data is expected in the third quarter of 2002 and patient enrollment is expected to continue through mid-2003.

As of early July 2002, a total of 72 patients had been enrolled in the four Phase 2 studies (18 per study). MTD in the colorectal study has been determined at 120 mg/m² per week, which corresponds to 360 mg/m² over a three-week period. As a comparison, the standard dose of Taxol is 175 mg/m² once every three weeks. MTD data for the other three Phase 2 studies is expected by the end of the third quarter 2002. Based on Phase 2 data to date from 39 of the 72 patients enrolled, there has not been a single case of any grade of neuropathy reported at any dose. Neuropathy, which is a numbness or tingling in the hands and feet, is a side effect commonly seen with Taxol and often limits a patient's ability to stay on therapy. Another side effect experienced with Taxol is neutropenia, a decrease in the white cell count. In the Phase 2 studies to date, results show that the rate of neutropenia for TOCOSOL Paclitaxel has been one third of that described in the Taxol package insert, which is based on once per three week dosing.

In addition to TOCOSOL Paclitaxel, we are evaluating other products and additional therapeutic drug formulations to expand our TOCOSOL drug delivery technology platform. We currently have several active compounds under investigation in therapeutic areas that target cancer, cardiovascular disease, diabetes and infection. In addition to injectable dosage forms, we are also seeing preliminary evidence supporting oral administration using the TOCOSOL technology platform in certain of these compounds. Our near-term objective is to file one Investigational New Drug (IND) application with the FDA by the end of 2002. Our research and development efforts on potential new products are preliminary and we cannot give any assurance that our efforts will be successful or that any INDs will be filed.

In June 2002, the Company entered into a manufacturing and supply agreement with Gensia Sicor Pharmaceuticals, Inc. for TOCOSOL Paclitaxel. The agreement provides the Company with a reliable manufacturer of the product for future clinical studies and commercialization requirements. Sonus and Gensia Sicor will collaborate to scale and validate the manufacturing process over the next 6 to 12 months.

Results of Operations

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

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

Historically, our reported revenues have been derived from payments received under contractual and license agreements with third parties. The Company reported no revenue in the second quarter of 2002 compared to \$91,000 for the second quarter of 2001. Revenues for the second quarter of the prior year represent royalty income under a prior agreement with Nycomed Amersham plc. For the six

months ended June 30, 2002, revenue was \$25,000 compared to \$1.2 million for the prior year period. Included in 2001 is a \$1.0 million non-refundable license fee payment received under an ultrasound contrast patent license agreement with Chugai Pharmaceutical Co. Ltd.

Total operating expenses were \$3.7 million for the second quarter of 2002 compared with \$1.9 million for the prior year. The increase in operating expenses from the prior year was primarily due to higher research and development expenses (\$2.8 million in the second quarter of 2002 compared to \$1.3 million in the second quarter of 2001). This planned increase was largely due to increased activity related to the manufacture, development and clinical testing of our lead cancer therapy product, TOCOSOL Paclitaxel, as the drug advances through phase 2 clinical trials as well as increased costs to support new product development. General and administrative expenses were also higher (8861,000 in the second quarter of 2002 compared to \$616,000 in the second quarter of 2001) primarily due to higher personnel and consulting costs. For the first six months of 2002, total operating expenses were \$6.2 million compared to \$3.8 million for the prior year period. The increase reflects the advancement of our lead product, TOCOSOL Paclitaxel, into phase 2 clinical trials, continued development of additional new drug compounds and higher personnel costs as we expand our operations.

We anticipate that total operating expenses for the next several quarters will be consistent with or slightly higher than the second quarter of 2002 as we continue to invest in current and future product development activities. Net cash burn for the full year 2002 is expected to be approximately \$13.0 to \$14.0 million.

Net interest income was \$150,000 and \$258,000 for the three and six months ended June 30, 2002 compared with \$107,000 and \$238,000 for the same periods in 2001. The increase in net interest income was primarily due to higher levels of invested cash in the current year, offset partially by lower interest rates.

Net loss for the second quarter of 2002 was \$3.5 million, compared with a net loss of \$1.7 million for the same period of the prior year. Net loss for the six months ended June 30, 2002 was \$6.0 million compared with a net loss of \$2.5 million for the same period of the prior year.

Liquidity and Capital Resources

We have historically financed operations with payments under contractual agreements with third parties and proceeds from equity financings. At June 30, 2002, we had cash, cash equivalents and marketable securities of \$22.1 million compared to \$15.1 million at December 31, 2001. The increase was primarily due to \$12.5 million of net proceeds from a private placement of common stock in January 2002, offset in part by the year-to-date net loss of \$6.0 million.

In June 2002, the Company entered into a manufacturing and supply agreement with Gensia Sicor Pharmaceuticals, Inc. for TOCOSOL Paclitaxel. Sonus and Gensia Sicor will collaborate to scale and validate the manufacturing process, and Sonus expects to spend approximately \$1.5 million over the next 6 to 12 months for the dedicated equipment and technology transfer to support these activities. Approximately \$1.0 million is expected to be incurred during the second half of this year and is included in the Company's previously disclosed projected 2002 net cash burn of \$13.0 to \$14.0 million.

We expect that our cash requirements will increase in future periods due to development costs associated with our TOCOSOL drug delivery products. Based on our current operating plan, including planned clinical trials and other product development costs including technology transfer costs related to our manufacturing and supply agreement, we estimate that existing cash and marketable securities will be sufficient to meet our cash requirements through 2003. However, we will need additional funding to complete late stage clinical trials and regulatory approval of TOCOSOL Paclitaxel and to

fund other product development activities beyond this timeframe. Accordingly, we intend to seek additional funding through available means, which may include debt and/or equity financing or funding under additional third party collaborative agreements. Our future capital requirements depend on many factors including:

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

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

Critical Accounting Policies and Estimates

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

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

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

Item 3. Market Risk

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

Part II. Other Information

Item 4. Submission of Matters to a Vote of Security Holders

Information regarding matters submitted to a vote of security holders at our annual meeting of stockholders held on April 23, 2002, is set forth in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2002.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

4.3	First Amendment to Rights Agreement, dated as of August 23, 1996, between the Company and U.S. Stock Transfer Corporation. (1)
10.52+	Manufacturing and Supply Agreement by and between the Company and Gensia Sicor Pharmaceutical Sales, Inc., dated June 26, 2002.
99.1	Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.2	Certification Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
+	Confidential treatment is being sought for certain portions of this Exhibit, as indicated by a "[*]" symbol and footnoted as "omitted pursuant to Rule 24b-2 and filed separately with the Commission." Such omitted portions have been filed with the Securities and Exchange Commission.
(1)	Incorporated by reference to exhibit number 2.1 to the Company's filing on Form 8-A12G/A dated July 25, 2002.

(b) Reports on Form 8-K

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

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

SIGNATURES

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

SONUS PHARMACEUTICALS, INC.

Date: August 13, 2002

By: /s/ Richard J. Klein

Richard J. Klein Vice President, Finance and Chief Financial Officer (Principal Financial and Accounting Officer) [Confidential treatment is being sought for certain portions of this Exhibit, as indicated by a "[*]" symbol and footnoted as "omitted pursuant to Rule 24b-2 and filed separately with the Commission." Such omitted portions have been filed with the Securities and Exchange Commission.]

MANUFACTURING AND SUPPLY AGREEMENT

This Agreement is made this 26th day of June, 2002 by and between Sonus Pharmaceuticals, Inc., a Delaware corporation having a principal place of business at 22026 20th Avenue S.E., Bothell, Washington 98021 ("Sonus") and Gensia Sicor Pharmaceutical Sales, Inc., a Delaware corporation having a principal place of business at 19 Hughes, Irvine, California 92618-1902 ("Gensia Sicor").

RECITALS

WHEREAS, Sonus is developing S-8184, also known as ${\tt TOCOSOL}({\tt TM})$ Paclitaxel, a cancer therapy product; and

WHEREAS, Gensia Sicor is in the business of developing, manufacturing, testing packaging, and marketing sterile injectable pharmaceutical products; and

WHEREAS, Sonus desires that Gensia Sicor manufacture and supply Sonus with certain of its requirements for S-8184; and

WHEREAS, Gensia Sicor desires to provide services to Sonus related to the manufacture of S-8184 as agreed to by both parties in accordance with the terms and conditions set forth herein

NOW THEREFORE, in consideration of the premises and the mutual promises and agreements contained herein, Sonus and Gensia Sicor agree as follows:

1. DEFINITIONS.

- 1.1 "Active Pharmaceutical Ingredient" or "API" means any component of the Product that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals, but does not include intermediates used in the synthesis of such ingredients.
- 1.2 "API Specifications" means the specifications for the API set forth in the Master Batch Record. A complete copy of the API Specifications, as agreed by the parties, is set forth in the API and Excipients Specifications attached as Exhibit A hereto.
- 1.3 "Affiliate" means, with respect to either party, all entities which, directly or indirectly, are controlled by, control, or are under common control with such party. For purposes of this definition, the word "control" shall mean ownership of more than fifty percent (50%) of the voting shares or interest of an entity.
- 1.4 "Batch" means the entire amount of Product yielded from a manufacturing event using a specific quantity of API, Excipients, and components Processed in accordance with the Master Batch Record.
- 1.5 "Batch Processing Charge" means the pricing set forth in Exhibit J, including the line batch charge, unit charge, compounding surcharge, and filter surcharge, as may be adjusted from time to time according to the terms and conditions set forth herein.
- 1.6 "Batch Record" means the document created as and after each Batch is Processed and Packaged. Each Batch Record shall reflect and incorporate all aspects of the Master Batch Record, the applicable Certificate of Analysis, and any Manufacturing Variance Reports issued with respect to such Batch.
- 1.7 "Batch Release" means the final sign-off by Gensia Sicor's Quality Department marking the culmination of the quality process by which a batch of Product is shown to conform to all aspects of the Manufacturing Standards.
- 1.8 "Compounded Bulk" means API and Excipients that have been compounded but not filled or packaged or finished into a final dosage presentation.
- 1.9 "Certificate of Analysis" means a certificate that accompanies each shipment of API, Excipient or Product certifying that the API, Excipient or Product meets the specifications as set forth in the Master Batch Record.
 - 1.10 "Current Good Manufacturing Practices" or "cGMPs" means the current

good manufacturing practices applicable to the manufacture of sterile pharmaceutical products for human use in the United States, as set forth in regulations promulgated by the FDA.

- 1.11 "Date of Manufacture" means the date of sterile filling of the Compounded Bulk.
- 1.12 "Excipient" means any substance, other than the API, used in formulating the Product.

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- 1.13 "Excipient Specification" means the specifications for the Excipient as set forth in the Master Batch Record. A complete copy of the Excipient Specifications, as agreed by the parties, is set forth in the API and Excipients Specifications attached as Exhibit A hereto.
- 1.14 "Facility" means Gensia Sicor's facility in Irvine, California, or any other Gensia Sicor facility as agreed to in writing, in advance, by the Parties to this Agreement.
 - 1.15 "FDA" means the United States Food and Drug Administration.
- 1.16 "Forecast" means a rolling twelve (12) month estimate of expected orders for the Product to assist Gensia Sicor in production planning.
- 1.17 "Manufacturing Standards" means the specifications for Processing, Packaging, and storing the Product set forth in the Product Specifications, the Master Batch Record, cGMPs, MSDSs, and all other applicable U.S. laws and regulations, to the extent such terms and conditions are not inconsistent with this Agreement.
- 1.18 "Manufacturing Variance Report" means a written report indicating any Variance in the Processing or Packaging of a Batch from the procedures set forth in the Master Batch Record.
- 1.19 "Master Batch Record" means the document, as may be amended from time to time, specifying: (i) the API and Excipient Specifications, (ii) the procedures for testing and releasing the API and Excipients, (iii) the Primary Components, (iv) Secondary Packaging, (v) the Product Specifications, (vi) the formula (listing the API and the Excipients for the Product), (vii) the procedures for manufacturing the Product (listing the API, the Excipients, the Primary Components, and the Secondary Packaging), and (viii) the procedures for assuring the quality of the Product.
- 1.20 "Master Forecast" means a [\star] forecast provided to Gensia Sicor for commercial product manufacturing.
- $1.21\ \hbox{"MSDS"}$ means the Material Safety Data Sheets for the API, Excipients and the Product, respectively.
- 1.22 "Package" or "Packaging" means the act of inspecting, labeling, and packing the Product into saleable units.
- 1.23 "Primary Components" means the vial, stopper, and seal as identified in the Master Batch Record.
- 1.24 "Process", "Processed" or "Processing" means the pharmaceutical manufacturing procedures, or any part thereof, involved in manufacturing the Product in accordance with the Master Batch Record.
- 1.25 "Product" means the finished emulsion cancer therapeutic product known as ${\tt TOCOSOL}$ (TM) Paclitaxel.

 \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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- 1.26 "Product Specifications" means the specifications for the Product, including the Primary Components, the Secondary Packaging, and the in-process and release specifications for the Product, as set forth in the Master Batch Record and as may be amended by the parties from time to time. A complete copy of the Product Specifications, as agreed by the parties, is set forth in the Product Description and Specifications attached as Exhibit B hereto.
- 1.27 "Purchase Order" means the document provided by Sonus to Gensia Sicor which shall set forth, subject to the terms of this Agreement, the number of Batches or units to be Processed and Packaged, the estimated Batch Processing Charge, the requested dates and locations for delivery, and special instructions for each Batch.

- 1.28 "Reference Standard" means a quantity of API or Excipient with a known assay, with which Gensia Sicor may perform comparative analysis to API or Excipient samples having an unknown assay.
- 1.29 "Registration Batch" means a batch of Product manufactured to support an NDA filing.
- 1.30 "Secondary Packaging" means any component other than Primary Components used to convert units of Product into saleable units.
- 1.31 "Shipping Components" means the packaging, boxes, and shipping containers into which the Product is placed for shipment to Sonus.
- 1.32 "Validation Batch" means a batch of saleable product manufactured prior to NDA approval to confirm that the process set forth in the NDA is reproducible at commercial scale, and which meets FDA requirements for a validation process.
- 1.33 "Variance" means a departure from an established quality standard (including, without limitation, cGMPs or other standard operating procedures, manufacturing work orders, Packaging orders, raw material or Product Specifications, analytical control procedures, water monitoring procedures, equipment maintenance schedules), whether anticipated or unanticipated, which has the potential to affect the safety, identity, strength, quality or purity of the Product.
- 1.34 "Work in Process" or "WIP" means the API, Excipients, Primary Components, and Secondary Packaging that constitute a Batch, during the time period beginning with Gensia Sicor dispensing API in accordance with the Master Batch Record and ending on the Gensia Sicor release date with respect to such Batch.

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- 2. ACQUISITION OF MANUFACTURING EQUIPMENT. Promptly after the execution of this Agreement, the parties shall confer and agree upon a list of the parts and equipment to be procured by Gensia Sicor on behalf of Sonus for the manufacturing of the Product. Sonus shall own all of such equipment so acquired. Gensia Sicor shall maintain customary insurance for the loss or damage to such equipment which shall name Sonus as a loss payee. The preliminary list of equipment to be purchased is set forth in Exhibit C attached hereto, which shall be finalized upon agreement of representatives of Sonus and Gensia Sicor. Gensia Sicor shall use commercially reasonable efforts to acquire the equipment and parts at the most favorable pricing available. All purchases of equipment will be made on a timely basis as needed and with the prior written approval of Sonus specifying the equipment and costs related thereto. The anticipated costs of the equipment are set forth on Exhibit C attached hereto. Sonus shall be responsible for payment of the purchase price of such equipment and the related administrative charge payable to Gensia Sicor, as provided in Section 6 below.
- 3. GENSIA SICOR PRE-COMMERCIAL RESPONSIBILITIES.

3.1 TECHNOLOGY TRANSFER.

- (a) Sonus shall transfer to Gensia Sicor the technology and expertise necessary to manufacture and supply the requirements of Sonus for the Product as provided herein. Sonus shall retain exclusive ownership of all patent, trademark, trade secret and other intellectual property rights relating to the technology, manufacturing process and information disclosed to Gensia Sicor. The parties' respective project representatives shall determine the analytical methods transfer and confirmation thereof; process evaluation, confirmation, optimization, and scale-up plan; cleaning validation; microbiology; method of media fills; component compatibility testing; production test run and other manufacturing procedures in order to finalize the scope of work and costs associated therewith. The anticipated costs shall include those related to such matters as more specifically itemized on Exhibit D attached hereto. In consideration of the services to be rendered by Gensia Sicor in connection with the technology transfer, Sonus shall pay to Gensia Sicor the fees as set forth on Exhibit D attached hereto in accordance with the terms and provisions of Section 6 below.
- (b) Gensia Sicor will develop a Master Batch Record for the Product following the technical specifications, methods and know-how provided by Sonus.
- (c) Sonus will transfer a stability indicating analytical method(s) for the Product to Gensia Sicor. Such methods will be validated by Gensia Sicor for their application to the finished Product. Upon Gensia Sicor's successful confirmation of validated stability indicating methods for Product Gensia Sicor will be responsible for release of finished dosage Product.
 - 3.2 PRE-COMMERCIAL MANUFACTURING RESPONSIBILITIES. In connection with

the validation and commercialization of the manufacturing process, the manufacturing of stability lots and clinical supplies and other pre-commercial manufacturing of the Product, Gensia Sicor shall have the following duties and responsibilities:

(a) Gensia Sicor shall establish manufacturing systems integration, including Batch Record development, SOP development and modifications, and raw material data sheet development.

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- (b) Gensia Sicor shall assist, as requested by Sonus, in the development of labeling and packaging for the Product, which will be submitted in regulatory submissions for the Product.
- (c) Gensia Sicor shall manufacture Registration Batches and perform process validation, including protocol development, implementation and final report.
- (d) As mutually defined and agreed by the project teams, Gensia shall conduct stability studies required for an NDA and other regulatory agency submittals.
- (e) Gensia Sicor shall provide regulatory support in the form of CMC documentation; sterility assurance package; process flow, facility narrative and report on testing.
- (f) Gensia Sicor shall validate and certify the manufacturing process, including installation qualifications, operational qualifications, and process qualifications for any new equipment or process used to support the manufacture of the Product.
- (g) Gensia Sicor shall provide suitable manufacturing instructions and other manufacturing documentation and manufacturing controls for NDA submission, as well as other regulatory submissions.
- (h) Gensia Sicor shall conduct material contact and equipment cleanability studies required to support manufacture of the Product in the Gensia Sicor manufacturing facility. Gensia Sicor shall complete any necessary sterility, microbial and pyrogen testing studies, and process validation studies, and provide Sonus or its representatives and appropriate regulatory agencies with microbiological data, process validation data, batch documents and other manufacturing and processing data required for FDA and other regulatory submissions.
- (i) Gensia Sicor will permit Sonus representatives to conduct necessary GMP and quality assurance reviews of Gensia Sicor documentation, including review of Gensia Sicor manufacturing work orders and manufacturing quality assurance Variances regarding the Product and the facilities in which the Product will be manufactured. In addition, Gensia Sicor shall host at least an annual quality assurance review of the Gensia Sicor manufacturing facility.

In consideration of the pre-commercial manufacturing services to be provided by Gensia Sicor, Sonus shall pay to Gensia Sicor, the fees set forth on Exhibit E attached hereto in accordance with the provisions of Section 6 below.

- 4. SONUS' PRE-COMMERCIAL RESPONSIBILITIES.
- 4.1 GENERAL RESPONSIBILITIES. Sonus shall have the following development duties and responsibilities with respect to the development of the Product:
- (a) Sonus shall promptly communicate to Gensia Sicor any changes to the Product formulation. In addition, to the extent necessary, Sonus shall verify that the U.S. Product formulation and associated specifications (modified as necessary) are acceptable as formulations for foreign countries.

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(b) Sonus shall provide approved API, Excipients and Reference Standards for the manufacture of pre-validation Product to Gensia Sicor, according to the provisions set forth in Section 8.3, with Certificates of Analysis, for formulation studies, stability and clinical supplies, manufacturing studies, and other needs as reasonably required by Gensia Sicor for execution of its responsibilities under this Agreement. Sonus shall provide API, Excipients and Reference Standards to Gensia Sicor at no charge at least fifteen (15) working days prior to any scheduled manufacture of Product. In the event that Sonus fails to deliver the quantity of conforming API, Excipients and Reference Standard required for Gensia Sicor to fulfill its obligations hereunder, Gensia Sicor shall not be obligated to meet scheduled delivery dates. API, Excipients and Reference Standard shall conform with the API and Excipient Specifications of Exhibit A, attached hereto and made a part hereof. Sonus shall

have the right to modify the API and Excipient Specifications from time to time in its sole discretion, in which event Exhibit A shall be so modified. All costs associated with implementing changes to the Master Batch Record shall be borne by Sonus, as per Exhibit G, subparagraph 2.1.

- (c) Sonus shall provide Gensia Sicor with technical data to enable Gensia Sicor to comply with its obligations under this Agreement. Such data shall include but not be limited to: (1) Material Safety Data Sheets with environmental and safety information; and (2) summaries of toxicological and pharmacological data for API and Excipients in sufficient detail to define potential hazards, establish employee exposure levels, and establish equipment cleanability limits.
- (d) Sonus shall perform and be responsible for conducting all clinical studies necessary to obtain FDA approval and regulatory approval from health authorities in foreign countries as determined by Sonus in its sole discretion.
- (e) Sonus shall conduct all research and development and use commercially reasonable efforts to prepare and submit to the FDA, and regulatory agencies in such foreign countries as Sonus shall deem appropriate in its sole discretion, an NDA or other regulatory submission covering the Product, respond to all questions from the regulatory agencies and take necessary steps to obtain regulatory agency approvals and maintain the approved NDA or other regulatory submissions covering the Product.
- (f) Sonus shall develop, proofread and maintain label copy and artwork for the Product. Sonus shall have complete responsibility for content and accuracy of labeling for Product provided that all labels and package inserts shall be developed in accordance with Gensia Sicor's guidelines with regard to physical dimensions and handling procedures.
- (g) Sonus shall review and approve the Master Batch Record in writing prior to initiating the manufacture of the Product, at least six (6) weeks prior to the scheduled manufacture of the batch. Material changes to the Batch Records shall be made at least six (6) weeks in advance of the manufacture of the next batch.

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5. SCHEDULE.

Both parties agree to use commercially reasonable efforts to conduct and complete the activities described in the foregoing Sections 2 through 4 with the goal of manufacturing the first clinical batch of the Product [*], according to the schedule appended hereto as Exhibit F.

6. PAYMENTS FOR GENSIA SICOR'S PRE-COMMERCIAL SERVICES.

To reimburse Gensia Sicor for its services and participation in the pre-commercial product development efforts, Sonus shall pay Gensia Sicor the following:

- 6.1 MANUFACTURING EQUIPMENT. As provided in Section 2 above, Sonus shall be responsible for payment of the purchase price of all equipment procured by Gensia Sicor on behalf of Sonus. In addition, Sonus shall pay Gensia Sicor an administration charge equal to [*]of the aggregate purchase price of all parts and equipment procured by Gensia Sicor for and on behalf of Sonus (excluding sales and other taxes, shipping, packing and other similar charges). Payment terms shall be as provided in Section 6.4 below.
- 6.2 TECHNOLOGY TRANSFER SERVICES. In consideration for the efforts and services to be rendered by Gensia Sicor regarding the transfer of manufacturing technology to Gensia Sicor as provided in Section 3.1 above, Sonus shall pay to Gensia Sicor the fees and expenses set forth on Exhibit D attached hereto. Payment terms shall be as provided in Section 6.4 below.
- 6.3 PRE-COMMERCIAL SERVICES. In consideration for the pre-commercial services to be provided by Gensia Sicor to Sonus as provided in Section 3.2 above and as more particularly specified on Exhibit E attached hereto, Sonus shall pay to Gensia Sicor the amounts set forth on Exhibit E. Payment terms shall be as provided in Section 6.4 below.

6.4 PAYMENT TERMS.

- (a) Sonus has paid [*] to Gensia Sicor as an advance for the purchase price of equipment and technology transfer services, which will be creditable against the acquisition of manufacturing equipment as provided in Section 6.1 above, and the technology transfer services as provided in Section 6.2 above.
- (b) With respect to payments due to Gensia Sicor for the purchase of equipment under this Section 6, except as covered by the advance provided for in subparagraph (a) above, all payment requests shall be submitted by invoice

from Gensia Sicor to Sonus promptly following receipt of an invoice from vendor of such equipment by Gensia Sicor.

(c) With respect to payments due to Gensia Sicor for services under this Section 6, except as covered by the advance provided for in subparagraph (a) above, [*] shall be due upon the initiation of a project and [*] shall be due upon completion and acceptance by Sonus of the work for the project. Initiation of any work or services on the project shall be authorized by Sonus in writing prior to the commencement of work by Gensia Sicor. All payment requests shall be submitted by invoice from Gensia Sicor to Sonus.

 \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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(d) Unless otherwise specifically provided, payment terms shall be net thirty days from the day of the Gensia Sicor invoice. Payment shall be in U.S. dollars. Terms shall be F.O.B. Gensia Sicor's Irvine, California facility.

6.5 CHANGES IN PROJECT SCOPE OR ADDITIONAL WORK. If material unanticipated changes occur in any Product development project or to the Product specifications, or if unanticipated technical difficulties result in the requirement for Gensia Sicor to perform material amounts of either additional or repeat work, or if additional work is required beyond the scope of a Product development project, which is not caused by the fault or negligence of Gensia Sicor, Gensia Sicor's reasonable costs for such additional work shall be paid by Sonus, subject to Sonus' prior written approval. Reimbursement for such additional work shall be at the rates specified on Exhibit G attached hereto, plus out-of-pocket costs for reasonable travel and subsistence, materials and supplies. Gensia Sicor shall provide Sonus with a new or revised scope of work with cost estimates for such additional work and shall receive the written approval of Sonus prior to commencing any such additional work. Sonus shall pay Gensia Sicor within thirty (30) days of receipt of an invoice confirming completion of such work.

7. REGULATORY MATTERS

7.1 SONUS' REGULATORY SUBMISSIONS FOR THE PRODUCT. Sonus shall be solely responsible for preparing and filing a NDA for the Product with the FDA and any applicable user fees for such, and for other regulatory submissions in such foreign countries as Sonus in its discretion deems appropriate. Sonus shall own the NDA and all other regulatory filings. Gensia Sicor agrees to cooperate and assist Sonus as Sonus may reasonably request in any such filings or submissions.

7.2 GENSIA SICOR'S MANUFACTURING LICENSES AND PERMITS. Gensia Sicor shall maintain all regulatory and governmental permits, licenses and approvals that are necessary for the manufacture of the Product and shipment of the Product to Sonus. During the term of this Agreement, Gensia Sicor will be responsible for any reporting of matters regarding the manufacture by Gensia Sicor of the Product to the FDA, or other applicable regulatory authority, as the case may be, in accordance with the applicable statutes and regulations. If any matters are reported directly to the FDA or other applicable regulatory authority, Gensia Sicor shall concurrently furnish copies of such reports to Sonus.

Gensia Sicor shall comply with all applicable laws and regulations, rules, ordinances, injunctions, orders and decrees, and shall maintain in effect all required governmental permits, licenses, orders, applications and approvals regarding the Product and the use of its Facility to Process or Package and store the Product, and Gensia Sicor shall Process or Package and store the Product in accordance with all such permits, licenses, applications and approvals.

Gensia Sicor shall be responsible to ensure that its Processing and/or Packaging and testing facilities, equipment and systems meet regulatory requirements for CGMPs for the United States and European Union. Gensia Sicor shall be responsible for validation of its Facility, equipment, Processing and/or Packaging processes as well as testing methods that apply to the Product. In addition, Gensia Sicor shall be responsible for all necessary education and training of its employees and contractors in regards to the Facility, equipment, Processing or Packaging, and testing methods that apply to the Product. The costs of such training will be borne by Gensia Sicor.

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7.3 MANUFACTURING INSPECTIONS. Gensia Sicor shall be responsible for handling and responding to any FDA or other regulatory authority inspections with respect to the manufacture by Gensia Sicor of the Product during the term of this Agreement. To the extent practicable, Gensia Sicor shall inform Sonus of

such inspections and shall permit a representative of Sonus to be present during those portions of such inspections that relate to the Product. Gensia Sicor shall provide to Sonus any information reasonably requested by Sonus and all information requested by any governmental or regulatory authority concerning any governmental inspection related to or affecting the Product. To the extent that Gensia Sicor requires the reasonable assistance of Sonus in order to fulfill its obligations pursuant to this Section 7.3, Sonus agrees to fully cooperate with and assist Gensia Sicor.

7.4 TRANSFER OF REGULATORY SUBMISSIONS. In the event, for any reason, Gensia Sicor is unable to supply Sonus with the Product pursuant to orders placed by Sonus hereunder, and shall fail to cure its failure within sixty (60) days of written notice from Sonus, Gensia Sicor shall promptly cooperate as reasonably required by Sonus to provide Sonus, or a designated third party of Sonus, under restrictions of confidentiality, such information, records and other documentation in Gensia Sicor's possession specifically relating to the manufacture of the Product as Sonus or such designated third party needs to supply the Product to Sonus, or which shall be reasonably required to transfer such records and documents as may be necessary to assure that any regulatory submissions by Gensia Sicor relating to the Product shall inure to the benefit of Sonus.

8. MANUFACTURE AND SUPPLY OF PRODUCT.

8.1 PURCHASE AND SALE OF PRODUCT. Pursuant to the terms and conditions of this Section 8, Gensia Sicor shall manufacture, sell and deliver Product to Sonus and Sonus shall purchase from Gensia Sicor at least [*] of the annual worldwide requirements of Sonus for the Product. Sonus shall have the right to manufacture the Product itself or to appoint third parties to manufacture for up to [*] of the worldwide requirements of Sonus for the Product. In the event Gensia Sicor is unable to supply Sonus with its requirements as set forth herein, Sonus shall have the right to itself manufacture or appoint a third party to manufacture Product. Sonus shall give Gensia Sicor six (6) months' prior notice in writing if Sonus decides to manufacture or have manufactured the Product by a third party. Gensia Sicor shall manufacture the Product in accordance with cGMPs per the approved manufacturing Batch Records and in accordance with the Product Specifications. The Product Description and Specifications are attached to this Agreement as Exhibit B and made a part hereof. Product Specifications may be changed from time to time upon approval by

8.2 GOVERNMENT APPROVALS. Notwithstanding any other provision of this Agreement, Gensia Sicor shall have no obligation to manufacture, sell or deliver Product to Sonus for commercial use until Sonus has obtained necessary government approvals required to manufacture and sell Product in the country into which the Product is intended to be sold.

* Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

8.3 SUPPLY OF API AND EXCIPIENTS. API and Excipients to be used in the manufacture of the Product, as specified in Exhibit A, shall be supplied/procured as follows:

Clinical and Stability Batches

Validation and Post-Validation Manufacture

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Excipients

Supplied by Sonus to Gensia Procured and supplied by Sicor at no cost. (With the Gensia Sicor from exception of sterile water for injection which shall be supplied by Gensia Sicor)

Sonus-approved sources.

API

Supplied by Sonus to Gensia Procured and supplied by at no cost.

Sonus at no cost to Gensia Sicor and to be shipped directly to Gensia Sicor by vendor.

transferred from Sonus to Gensia Sicor at any other time that may be mutually agreeable to the parties, provided that sufficient lead time is allowed to procure material for scheduled production batches. Gensia Sicor shall use commercially reasonable efforts to obtain such API and Excipients at the most favorable pricing available. Sonus shall reimburse Gensia Sicor for the cost of such API and Excipients obtained by Gensia Sicor on behalf of Sonus according to the provisions of Section 8.5 (c), below.

8.4 MANUFACTURE OF PRODUCT.

- (a) Gensia Sicor shall provide such facilities, equipment, and services as may be required to perform the Processing, Packaging and handling of such Product in accordance with the manufacturing and control procedures set forth in the Master Batch Record and the terms and conditions set forth herein. Gensia Sicor shall manufacture Product for Sonus from the API and Excipients supplied by Sonus to Gensia Sicor and /or API and Excipients obtained by Gensia Sicor as per Section 8.3 above. Gensia Sicor will obtain other materials and components for production from qualified suppliers approved by Gensia Sicor. To insure Gensia Sicor's ability to manufacture Product in accordance with Sonus' orders, Sonus shall provide to Gensia Sicor at Gensia Sicor's manufacturing plant the API and Excipients at least two weeks prior to the scheduled manufacturing date. API and Excipients shall be delivered F.O.B. Gensia Sicor's plant pursuant to no-cost purchase orders issued by Gensia Sicor to Sonus. Sonus warrants to Gensia Sicor that the API and Excipients supplied to Gensia Sicor hereunder shall meet the specifications set forth in Exhibit A, as may be modified from time to time by Sonus, and shall be suitable for use in the manufacture of Product. The API and Excipients shall be accompanied by a Certificate of Analysis.
- (b) Any proposed change to the Master Batch Record or Product Specifications must be approved by both Parties. Any resulting increase or decrease in Gensia Sicor's production costs shall be supported by documentation in form and content reasonably satisfactory to Sonus. If Sonus elects to adopt the revision, the Batch Processing Charge will be increased or decreased by the amount of such changes in production costs, and the related Schedules will be amended accordingly.

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- (i) If Gensia Sicor determines it is technically unable to comply with a proposed revision of the Master Batch Record or the Specifications, or if Sonus is unwilling to accept any increase in the Batch Processing Charge arising therefrom, Sonus may choose in its sole discretion to either withdraw the proposed revision or terminate the Agreement.
- (ii) No revisions to the Specifications that would affect the Processing and/or Packaging of the Product shall be submitted to any Regulatory Authorities unless approved by both Parties in writing. It is understood by both Parties that changes mandated by Regulatory Authorities shall be acted upon with due diligence.
- (iii) Gensia Sicor shall not change the geographical location at which it Processes the Product nor shall it make any material change to the facilities used to Process the Product without providing Sonus with prior written notification. All costs associated with a facility change or modification that is requested by Sonus shall be the responsibility of Sonus. All costs associated with a facility change or modification that is imposed by the FDA or any other regulatory body to comply with cGMP shall be the responsibility of Gensia Sicor, unless such change relates solely to, or was caused solely by, the Product.
- (c) Risk of loss of API, Work in-Process and finished Product held by Gensia Sicor on its premises and in its care, custody and control, shall be with Gensia Sicor until shipped as Product or otherwise to Sonus, except as provided for in this Section. Notwithstanding the foregoing, Gensia Sicor shall not be liable for loss of API, Work in-Process or finished Product when Gensia Sicor is conducting manufacturing operations in accordance with Gensia Sicor's SOPs, cGMPs and the procedures as set forth in the Master Batch Record, except as set forth below.
 - (i) In the event of a failed Batch, Gensia Sicor shall be liable to Sonus only if the cause of such a failure is attributable primarily to the negligence or willful conduct of Gensia Sicor. In that case, Gensia Sicor shall, as Sonus' sole and exclusive remedy for the failed Batch, not invoice Sonus for the failed Batch and Sonus may choose one of the following two options:
 - Option 1: Gensia Sicor will pay Sonus an amount equal to the lesser of (i) the value of the lost API or (ii) the Line Batch Charge as set forth in Exhibit J.
 - Option 2: Gensia Sicor will use commercially reasonable efforts to remanufacture the Batch as soon as practical, and apply a

credit to the invoice for the replacement batch in an amount that is the lesser of (i) the value of the lost API or (ii) the Line Batch Charge as set forth in Exhibit J.

Notwithstanding the foregoing, if the cause of such a failure is due to equipment failure (other than equipment specified by Sonus and maintained by Gensia Sicor in accordance with manufacturer's recommendations), operator error or accident, Sonus will not be charged the Batch Processing Charge.

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Gensia Sicor shall assume no liability for Product that fails to conform with the Manufacturing Standards if the Product: (i) has been subjected to misuse, negligence or accident other than by Gensia Sicor or any employee or agent of Gensia Sicor; (ii) has been stored, handled or used by others in a manner contrary to current good manufacturing practices or similar requirements after delivery to a common carrier; or (iii) nonconformance is attributable to processes, procedures or Product components specified by Sonus in the Master Batch Record where such processes, procedures or Product components were followed or used by Gensia Sicor in accordance with the Master Batch Record

- (ii) In the event of loss of API prior to the start of the manufacturing process, Gensia Sicor shall be liable to Sonus only if the cause of such a failure is attributable primarily to the negligence or willful conduct of Gensia Sicor. In that case, Gensia Sicor shall, as Sonus' sole and exclusive remedy for the lost API, pay to Sonus an amount that is equal to the value of the lost API.
- (iii) Gensia Sicor shall not be liable for loss of API, Compounded Bulk, WIP, or Product; (1) resulting from an event of force majeure; (2) caused by Sonus' negligence or willful misconduct; (3) [*]; or (4) occurring while Gensia Sicor is actually conducting manufacturing operations in accordance with the Manufacturing Standards, except as specified in subparagraph (e) below.
- (d) Adequate storage space shall be provided for the API, Excipients and finished Product, on-site at Gensia Sicor. Gensia Sicor shall maintain and monitor API, Excipients and finished Product temperature where specified. In the event Sonus requests Gensia Sicor to store Product after it has been released, Gensia Sicor shall store the Product as storage capacity allows for a reasonable time at the rates set forth on Exhibit H. Gensia Sicor will store the Product at no charge for up to fifteen (15) calendar days following Gensia Sicor Batch Release. In the event that Sonus requires a delay in shipment of finished Product and Sonus communicates such change in writing prior to Gensia Sicor Batch Release, Gensia Sicor will either transfer the Product to a Sonus specified pharmaceutical warehouse or, as space permits, store the finished Product and invoice Sonus for the Batch(s).
- (e) Normal inventory and yield loss for API and Excipients ("Standard Batch Yield") shall be established by agreement of the parties after three (3) full validation runs plus three (3) commercial runs of saleable Product. The Standard Batch Yield shall be reviewed and may be modified on an annual basis upon mutual consent of the parties taking into consideration Gensia Sicor's actual manufacturing experience with the Product. In the event that a commercial batch yields less than the Standard Batch Yield by more than [*], Gensia Sicor shall reimburse Sonus for the cost of the amount of wasted API and Excipients provided by or paid for by Sonus, at the then current cost, however, in no event shall reimbursement by Gensia Sicor under this Section 8.4(e) exceed an amount equivalent to the Line Batch Charge set forth on Exhibit J.
- (f) Product shall be labeled by Gensia Sicor in accordance with label copy provided by Sonus, which shall have been approved by the appropriate regulatory agency. Such copy may be modified from time to time by Sonus. All costs associated with labeling changes shall be borne by Sonus. Product labeling shall contain the trademarks designated by Sonus. Primary and

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secondary labeling shall acknowledge and name Gensia Sicor Pharmaceuticals as the manufacturer of the Product.

 $^{^{\}star}$ Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

Product for Sonus shall be applied in the same manner as those procedures and checks are applied to other products manufactured by Gensia Sicor and shall include procedures specified on Exhibit I attached hereto. A Certificate of Analysis shall be provided to Sonus at the time Product is delivered hereunder.

- (h) Sonus shall have a period of twenty-five (25) days from the date of receipt by Sonus to inspect and reject any shipment of Product on the grounds that it does not conform with the Product Description and Specifications. If the Product is delivered by Gensia Sicor directly to customers, the inspection period shall be twenty-five (25) days from the receipt of the Product by the customer. Sonus shall have the right to return any Product that does not conform. Sonus shall be deemed to have accepted delivery of Product if no notice of rejection is received by Gensia Sicor in accordance with the procedure and time frame described herein. No claims with respect to rejected Product shall be greater than the sum of the cost of replacement of API or Excipients as set forth in subparagraph (b) above plus the Purchase Order price for the non-conforming Product. All or part of any shipment may be held for Gensia Sicor's disposition and at Gensia Sicor's expense if found to be not in conformance with the Product Specifications, provided Gensia Sicor confirms such nonconformance through generally accepted quality control procedures, and provided further that such nonconformance is not due to the failure of the API or Excipients supplied by Sonus hereunder to conform to the specifications therefor. If the parties disagree with respect to whether Product is nonconforming, the Product in question shall be submitted for testing to an independent testing laboratory acceptable to both parties. The parties further agree that the determination of such independent laboratory shall be binding on both parties and that the cost related to such testing shall be paid by the party that was in error with respect to whether the Product is nonconforming. Any Product not rejected by Sonus pursuant to this subparagraph 8.4(f) shall be deemed accepted.
- (i) Sonus shall reimburse Gensia Sicor for the actual cost of any obsolete Excipients, Primary Components, Shipping Components, and Secondary Packaging, (plus any related special disposal costs) purchased by Gensia Sicor expressly to meet its performance obligations under this Agreement in reliance upon Sonus' then most recent Forecast, except in the case where such obsolete Excipients, Primary Components, Shipping Components and Secondary Packaging were purchased by Gensia Sicor greater than three (3) months before scheduled use. An obsolete component is any Excipient, Primary Component, Secondary Packaging, or Shipping Component which cannot be incorporated into the Product due to changes directed by Sonus or mandated by a regulatory authority, or caused by a cancellation or postponement of manufacturing. Once a component becomes obsolete, Gensia Sicor may invoice Sonus the acquisition cost of such obsolete components, which invoice shall identify the Excipients or components in question and shall be accompanied by a reasonably detailed statement of the cause of such obsolescence. Any such obsolete component(s) shall be returned to Sonus and Sonus' discretion and expense.
- (j) If any Product must be recalled by reason of failure to meet any requirements of any regulatory authority or any other requirements of law or if an NDA Field Alert must be issued, Sonus shall have the sole responsibility to effect such recall or issue such Field Alert. Sonus shall consult with Gensia Sicor prior to effecting any such recall or issuing any such NDA Field Alert. Gensia Sicor shall cooperate as reasonably required in Sonus' efforts. The parties shall have the following duties and responsibilities in connection with any such recall:

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(i) Sonus' Responsibility.

If the failure to meet applicable legal requirements resulting in a recall or issuance of an NDA Field Alert is not caused by the act or omission of Gensia Sicor, then Sonus shall reimburse Gensia Sicor for any costs reasonably expended by Gensia Sicor to effect the recall. Sonus shall bear the cost of (a) the Batch Processing Charge for any Product that is recalled and (b) reimburse Gensia Sicor on a time and materials basis not to exceed the Batch Processing Charge, for any Work-in-Process, Finished but non-approved Product, or Product that cannot be shipped due to the condition requiring the recall, provided that as of the date that the Processing and/or Packaging was suspended as a result of the recall, such Work-in-Process had been Processed and/or Packaged in accordance with the Master Batch Record and/or Master Packaging Record, and the non-approved Product and/or unshipped Product conforms in all material aspects to the Specifications and was Processed and/or Packaged in accordance with the Processing and/or Packaging, Quality Assurance and Validation procedures set forth in the Specifications and with any applicable regulations of any Regulatory Authorities, including cGMPs.

If the failure to meet applicable legal requirements resulting in a recall or issuance of an NDA Field Alert is caused by an act or omission of Gensia Sicor, or by the breach of Gensia Sicor's warranties under this Agreement, or if the Product failed to conform to any of the Specifications resulting in a recall or issuance of an NDA Field Alert, Gensia Sicor shall reimburse Sonus for (a) any cost reasonably expended by Sonus to effect the recall or issue the NDA Field Alert, and (b) any Batch Processing Charge paid to Gensia Sicor by Sonus for recalled Product and for any Product that cannot be shipped due to the condition requiring the recall or NDA Field Alert.

(iii) Cooperation.

Gensia Sicor shall cooperate as reasonably required to allow Sonus to determine the root cause of the problem resulting in a recall or Field Alert. Such assistance shall include follow-up investigation including reviews of retained samples and Batch Records as well as testing of Product. Gensia Sicor shall provide Sonus within five (5) business days from the date of request all necessary information that will enable Sonus to respond properly to issues relating to the recall or Field Alert. Gensia Sicor shall also cooperate fully in resolving Product issues.

(k) Sonus shall have the right, upon reasonable written notice to Gensia Sicor, to conduct once each calendar year and during normal business hours a quality assurance audit and inspection of Gensia Sicor's records and production facilities relating to manufacture of the Product.

(1) If requested by the FDA or other regulatory agency, either party may provide a copy of this Agreement to the FDA or other regulatory agency with selected financial and business terms redacted. In such event the party providing the copy shall immediately notify the other party that a copy has been or will be provided to the FDA or other regulatory agency. The parties further acknowledge that either party may be required to file this Agreement under federal securities laws.

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(m) Gensia Sicor shall maintain hazard and liability insurance which shall cover loss or damage to API or Work in Progress. Wherever loss as described in this Section 8.4 is covered by insurance held by Gensia Sicor, the first recourse for recovery of loss shall be through such insurance and to the full extent of the loss, notwithstanding any other limitations set forth in this Section 8.4.

(n) Wherever loss as described in this Section 8.4 is limited to the amount of the Line Batch Charge as set forth in Exhibit J, that limit shall be the greater of the current Line Batch Charge or [*] which is the Line Batch Charge as of the date of execution of this Agreement.

8.5 PRICE AND PAYMENT.

(a) Product shall be delivered by Gensia Sicor at the prices set forth in Exhibit J of this Agreement. The pricing set forth on Exhibit J shall remain in effect from the date of this Agreement through [*]. Thereafter, the pricing may be increased by Gensia Sicor by an amount not to exceed the annual percentage increase of the Producer Price Index, pharmaceutical preparations, issued by the Bureau of Labor Statistics, the U.S. Department of Labor. The pricing includes related services for (i) supplying cGMP compliant facilities, equipment and processes, (ii) maintenance, calibration and monitoring of all utility systems, (iii) microbiological monitoring of controlled environments, (iv) processing supplies, (v) manufacturing production, (vi) one manufacturing day and necessary labor and resources to support the manufacture of one batch of Product, (vii) personnel training, (viii) system maintenance of SOPs and Batch Records, and (ix) completion of Batch Record reviews and product releases within forty-five (45) days of initiating manufacture. The prices do not include any labeling or packaging development or other preparatory or other work requested by Sonus. Gensia Sicor shall invoice Sonus for such labeling and packaging development or other work according to the pricing set forth on Exhibit E attached hereto. Gensia Sicor may revise the Batch Processing Charge, upon written notification to Sonus, should new processes or procedures be required for the safe manufacture and clean-up of the Product, provided that Gensia Sicor, Sonus and appropriate vendor(s) will collaborate to minimize such

(b) Gensia Sicor shall offer to Sonus the benefit of any volume-based price adjustments or other discount programs that it makes available to any other customers for comparable utilization of Gensia Sicor facilities or resources at the same time as Gensia Sicor provides any such benefit to its other customers.

(c) Gensia Sicor shall be responsible for payment of the purchase

price of all API and Excipients procured by Gensia Sicor for and on behalf of Sonus, except as provided in Section 8.4 (a) and (b). Gensia Sicor shall invoice Sonus for reimbursement for the aggregate purchase price of all such API and Excipients procured. In addition, Sonus shall pay Gensia Sicor an administration charge equal to [*] of the aggregate purchase price of all API and Excipients procured by Gensia Sicor for and on behalf of Sonus (excluding sales and other taxes, shipping, packing and other similar charges).

 \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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- (d) In addition, upon request by Sonus, Gensia Sicor shall provide miscellaneous support services, including Batch Record modification, excipient testing and Batch Release testing for the prices set forth on Exhibit G attached hereto.
- (e) Gensia Sicor shall invoice Sonus upon delivery of Product to Sonus for each batch manufactured by Gensia Sicor the sum of the Batch Processing Charge as specified on Exhibit J. The price for one batch of Product includes one manufacturing production day and necessary labor and resources to manufacture one batch of Product. A late payment service charge of 1.5 percent per month (or the highest amount permitted by law, if lower than 1.5 percent) shall be paid on all amounts that are past due more than thirty (30) days from the date of invoice, which shall not be submitted to Sonus prior to Batch Release.
- (f) Any federal, state, county or municipal sales or use tax, excise or similar charge, or any other tax assessment (other than that assessed against income), license, fee or other charge lawfully assessed or charged on the sale or transportation of Product sold pursuant to this Agreement shall be paid by Sonus.
- 8.6 DELIVERY. Upon Gensia Sicor's release, the finished Product shall be shipped to Sonus, or another location specified by Sonus on a corresponding Purchase Order. Shipping costs, which shall be described as commercial freight ground service per Gensia Sicor's selected carrier, or the carrier or method of shipment as specified by Sonus, shall be borne by Sonus. Any additional shipping costs, including temperature monitors if required, will be borne by Sonus and will be invoiced at the actual rate, plus any additional out-of-pocket charges for delivery services. Product shall be delivered to Sonus F.O.B. Gensia Sicor's facility in Irvine, California and title shall pass to Sonus at such point. Gensia Sicor will not be liable for loss or damage to the Product resulting from the shipping of Product subsequent to its delivery to the common carrier.

8.7 ORDERS AND FORECASTS.

- (a) Upon execution of this agreement, Sonus shall supply Gensia Sicor with a Forecast for the Product, and update it [*]. For clinical Product Gensia Sicor acknowledges that the Forecast is an estimate and shall not be binding.
- (b) At least [\star] prior to the first forecasted commercial sale of the Product, and thereafter [\star], Sonus shall supply Gensia Sicor with a rolling Forecast of the quantities of the Product Sonus intends to order during the following [\star] period. Estimated demand for Product shall be communicated [\star]. The first [\star] of the Forecast shall constitute a firm order and a binding commitment. The last [*] of each Forecast shall constitute a good faith estimate of expected orders for the Product to assist Gensia Sicor with production planning.
- (c) In addition to a rolling [*] Forecast, Sonus shall supply Gensia Sicor with a Master Forecast on the following schedule:
 - [*] prior to commercial launch, then;

 - Prior to either [*], whichever comes first, then;
 [*] after the latest submission of the Master Forecast, then;
 - 4. Prior to [*] in all subsequent years

 $[\]star$ Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

for each [*] not supplied. If any failure to meet the purchase obligation under the Master Forecast results from cancellation of any order for which a fee is payable under subparagraph (h) below, the total fee payable for any [*] not supplied shall be [*].

- (d) Sonus shall place each Purchase Order with Gensia Sicor for Product to be delivered hereunder at least [*] prior to the requested delivery date specified in each respective Purchase Order. Gensia Sicor will deliver written confirmation of receipt of each Purchase Order and the anticipated delivery date of Product to Sonus within [*] of receipt by Gensia Sicor. Sonus shall be obligated to purchase all Product ordered and delivered by the specified delivery date.
- (e) Gensia Sicor may reject any Purchase Order that exceeds [*] of the [*] forecasted in the Master Forecast. No rejection shall be effective unless in writing and delivered to Sonus within [*] of Gensia Sicor's receipt of Sonus' Purchase Order. Gensia Sicor will use commercially reasonable efforts to meet Sonus' requests for [*] in excess of those set forth in the Master Forecast, provided, however, that no breach of this Agreement shall occur if Gensia Sicor, despite its commercially reasonable efforts, is unable to supply such quantities of Product to Sonus.
- (f) Each Purchase Order for Product shall be governed by the terms of this Agreement and none of the provisions of such Purchase Order shall be applicable except those specifying quantity ordered, delivery dates, special shipping instructions and invoice information.
- (g) Sonus shall have the right to audit Gensia Sicor's records during normal business hours, from time to time, to confirm that the provisions of this Agreement are being applied as specified.
- (h) In the event Sonus cancels or postpones Processing prior to the manufacturing date communicated to Sonus pursuant to this Section 8.7, Gensia Sicor shall use commercially reasonable efforts to reschedule the postponed order to a date agreeable to both Parties. If Sonus does not reschedule the date of manufacture to a date within [*] of the originally scheduled date, the Purchase Order shall be considered cancelled. Sonus may postpone a Purchase Order [*]. Sonus shall reimburse Gensia Sicor for all unique supplies and components acquired for Sonus in the event of cancellation of any manufacturing run. If a manufacturing date is cancelled or postponed by Sonus, Sonus may be charged a cancellation fee in accordance with the following:

* Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

CANCELLATION / POSTPONEMENT FEE

Notice of cancellation /postponement received [*] as set forth in Exhibit J.

Notice of cancellation / postponement received [*]
less than [*] from the scheduled fill date

Notice of cancellation / postponement received [*]
less than [*] from the scheduled fill date

Notice of cancellation / postponement received [*]
less than [*] from the scheduled fill date

Notice of cancellation / postponement received [*]
less than [*] from the scheduled fill date

8.8 WARRANTIES.

(a) Sonus represents and warrants to Gensia Sicor that API and Excipients to be delivered to Gensia Sicor pursuant to this Agreement, at the time of delivery, (i) shall conform to the specifications for such API and Excipients, and (ii) shall not be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, as amended, or within the meaning of any applicable state or municipal law in which the definitions of adulteration

and misbranding are substantially the same as those contained in the Federal Food, Drug and Cosmetic Act, as well as any applicable foreign law or regulation of any country in which the Product will be sold, as such Act and such laws are constituted and effective at the time of delivery and shall not be an article which may not under the provisions of Sections 404 and 505 of such Act be introduced into interstate commerce.

- (b) Gensia Sicor represents and warrants to Sonus that Product delivered to Sonus pursuant to this Agreement shall, at the time of delivery, not be adulterated or misbranded within the meaning of the Federal Food, Drug and Cosmetic Act, as amended, or within the meaning of any applicable state or municipal law in which the definitions of adulteration and misbranding are substantially the same as those contained in the Federal Food, Drug and Cosmetic Act, as well as any applicable foreign law or regulation of any country in which the Product will be sold, as such Act and such laws are constituted and effective at the time of delivery and shall not be an article which may not under the provisions of Sections 404 and 505 of such Act be introduced into interstate commerce.
- (c) Gensia Sicor represents and warrants that Product delivered to Sonus pursuant to this Agreement shall be manufactured in an FDA approved facility in accordance with the term of this Agreement and current Good Manufacturing Practices, as promulgated by the FDA, and shall conform with the Product Description and Specifications of Exhibit B. Gensia Sicor further warrants that Product delivered to Sonus pursuant to this Agreement shall be manufactured in accordance with applicable laws and regulations of regulatory agencies of other countries in which the Product will be sold. The foregoing warranties shall not extend to any nonconformity or defect which relates to or is caused by API or Excipients supplied to Gensia Sicor by Sonus.
 - \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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- (d) NEITHER PARTY MAKES ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE API, EXCIPIENTS OR THE PRODUCT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY DISCLAIMED BY GENSIA SICOR. Neither party shall be liable to the other for any indirect, incidental, special or consequential damages resulting from any breach of this Agreement.
- (e) Gensia Sicor shall indemnify, defend and hold Sonus harmless from and against all claims, causes of action, settlement costs, including reasonable legal expenses, losses or liabilities of any kind asserted by third persons which arise out of or are attributable to (i) any negligent act or omission or willful misconduct on the part of Gensia Sicor's employees, agents or representatives, or (ii) any breach by Gensia Sicor of any term or provision of this Agreement. Sonus shall indemnify, defend and hold Gensia Sicor harmless from and against all claims, causes of action, settlement costs, including reasonable legal expenses, losses or liabilities of any kind asserted by third persons which (i) arise out of or are attributable to any negligent act omission or willful misconduct on the part of Sonus' employees, agents or representatives, or (ii) any breach by Sonus of any term or provision of this Agreement, or (iii) involve the use of the Product as a pharmaceutical product, or the safety or efficacy of the Product and which are not otherwise attributable to any indemnification claim of Sonus pursuant to the preceding sentence.
- (f) Sonus shall indemnify, defend and hold Gensia Sicor harmless from and against any damage, judgment, loss, cost or other expense, including reasonable legal expenses, arising from claims that the Product or its manufacture, use or sale infringes patent or other proprietary rights of a third party provided that the infringement does not relate solely to the manufacturing procedures of Gensia Sicor.
- (g) If either party expects to seek indemnification from the other under the preceding three subparagraphs, the party seeking indemnification shall promptly give notice to the other party of any such claim or suit threatened, made or filed against it which forms the basis for such claim of indemnification and shall cooperate fully with the other party in the investigation and defense of all such claims or suits. The indemnifying party shall have the option to assume the other party's defense in any such claim or suit with counsel reasonably satisfactory to the other party. No settlement or compromise shall be binding on a party hereto without its prior written consent, unless such settlement fully releases the other party without any liability, loss, cost or obligation to such party.
- (h) In the event (a) any government authority issues a request, directive or order that the Product be recalled, or (b) any court of competent jurisdiction order such a recall, or (c) Sonus, after consultation with Gensia

Sicor determines that the Product should be recalled, then in any such event, the parties shall have the respective duties and obligations set forth in Section 8.4(j) above, and take all appropriate corrective actions, and shall cooperate in the investigations surrounding the recall. Sonus shall have the sole responsibility of notifying customers and return of Product from customers, as well as all FDA communications and requests regarding any such recalls.

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9. TERM AND TERMINATION.

- 9.1 This Agreement shall commence on the date first above written and the initial term shall expire [*] following market introduction of the Product; provided, however, that if market introduction of the Product has not occurred within [*] from the date of this Agreement, either party may terminate this Agreement upon ninety (90) days prior written notice to the other party. Thereafter, the term shall continue automatically for successive two (2) year periods until terminated, upon not less than twelve (12) months prior written notice from one party to the other.
- 9.2 Either party may terminate this Agreement by giving to the other sixty (60) days prior written notice upon the bankruptcy or the insolvency of the other party.
- 9.3 Either party may terminate this Agreement upon the breach of any material provision of this Agreement by the other party if the breach is not cured within sixty (60) days after written notice thereof to the party in default.
- 9.4 Either party may terminate this Agreement with sixty (60) days written notice should the manufacture of the Product be deemed unfeasible, and only after commercially reasonable efforts have been applied to resolve the circumstance that is deemed the cause of the manufacture being unfeasible. Circumstances that could cause the manufacture of the Product to be deemed unfeasible include, but shall not be limited to, [*] and failure to manufacture the Product in accordance with the [*].
- 9.5 Upon any termination of this Agreement, Gensia Sicor shall return to Sonus all manufacturing equipment and parts, API, Excipients, and other materials and supplies which Sonus has supplied to Gensia Sicor or has paid for pursuant to the terms of this Agreement. All such items shall be returned F.O.B. Gensia Sicor's facility in Irvine, California and Sonus shall be solely responsible for all packing, shipping and related charges.
- 9.6 Termination, expiration, cancellation or abandonment of this Agreement through any means and for any reason shall not relieve the parties of any obligation accruing prior thereto and shall be without prejudice to the rights and remedies of either party with respect to any antecedent breach of any of the provisions of this Agreement.

10. CONFIDENTIAL INFORMATION.

It is recognized by the parties that during the term of this Agreement the parties shall exchange Confidential Information. "Confidential Information" shall mean all information, including where appropriate without limitation, any information, patent disclosures, patent applications, structures, models, techniques, processes, compositions, compounds and apparatus relating to the same, disclosed by one party (the "disclosing party") to the other party (the "recipient") or obtained by the recipient through observation or examination of such information, but only to the extent that such information is maintained as confidential by the disclosing party. Gensia Sicor acknowledges that all information relating to the Specifications of the Product and the active ingredient for the Product, and all manufacturing processes and procedures for the Product which are disclosed by Sonus to Gensia Sicor, constitute Confidential Information and are exclusively owned by Sonus. Gensia Sicor agrees that it shall not disclose Confidential Information received from

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Sonus, and shall not use Confidential Information disclosed to it by Sonus for Gensia Sicor's benefit (other than in the performance of its obligations hereunder) or for the benefit of any third person. Sonus agrees that it shall not disclose confidential Information received from Gensia Sicor, and shall not use Confidential Information disclosed to it by Gensia Sicor for Sonus' benefit (other than in the performance of its obligations hereunder) or for the benefit of any third person. For purposes of this Agreement, Confidential Information shall include all information disclosed hereunder in writing and identified as

 $[\]star$ Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

confidential or if disclosed orally is reduced to writing within thirty (30) days of oral disclosure and identified as confidential, except any portion thereof which:

- (a) the recipient can prove was known to the recipient before receipt hereof under this Agreement;
- (b) is disclosed in good faith to the recipient after acceptance of this Agreement by a third person lawfully in possession of such information and not under an obligation of nondisclosure;
- (c) is or becomes part of the public domain through no fault of the recipient;
- (d) the recipient can prove was developed by the recipient independently of information disclosed hereunder; or
- (e) is required by law to be disclosed; provided, however, that no disclosure shall be made pursuant to this clause (e) unless prior notice is given to the disclosing party and the disclosing party shall have a reasonable opportunity to prevent such disclosure or take appropriate preventative precautions relating to such disclosure.

In the case of clauses (a), (b) and (d) above, the exception must be proven by clear and convincing evidence and evidence of prior knowledge must be in the form of a document dated prior to the disclosure by the disclosing party. Notwithstanding the above, nothing contained in this Agreement shall preclude Sonus or Gensia Sicor from utilizing Confidential Information as may be necessary in prosecuting patent rights of the parties with respect to inventions solely owned by that party, or obtaining governmental marketing approvals for Product, or in manufacturing Product pursuant to this Agreement. The obligations of the parties relating to Confidential Information shall expire five (5) years after the termination of this Agreement.

The provisions of this paragraph 9 are in addition to the provisions of the confidential disclosure agreement entered into between Sonus and Gensia Sicor on May 4, 2001.

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11. IMPROVEMENTS.

- 11.1 GENSIA SICOR PROCESS IMPROVEMENTS. Any developments, inventions or discoveries developed or acquired solely by Gensia Sicor during the term of this Agreement and which are applied to the manufacture of the Product shall be owned solely by Gensia Sicor ("Gensia Sicor Process Improvements"). Sonus shall have a royalty-free, non-exclusive, perpetual license to such Improvements relating solely to the manufacture of the Product, whether such Improvements are patentable, patented, or kept by Gensia Sicor as proprietary know-how or trade secret, provided that the Product is manufactured by Gensia Sicor. In the event Sonus licenses the right to develop, market and distribute the Product to a third party who is not an Affiliate of Sonus, and such licensee desires to transfer the manufacturing of the Product to a manufacturer other than Gensia Sicor, and Gensia Sicor does not retain manufacturing rights pursuant to Section 12, Gensia Sicor shall negotiate in good faith to license all or any Gensia Sicor Process Improvements to such third-party manufacturer on commercially reasonable terms.
- 11.2 SONUS IMPROVEMENTS. Any developments, inventions or discoveries related to the manufacture of the product developed or acquired solely by Sonus during the term of this Agreement shall be owned solely by Sonus.
- 11.3 GENSIA SICOR AND SONUS IMPROVEMENTS. For any Improvements of Gensia Sicor and Sonus jointly which relate to the manufacture of the Product, Gensia Sicor and Sonus shall have joint rights to the Improvements, and all patents or other intellectual property rights pertaining thereto. Joint improvements include Improvements developed, made or conceived jointly by Gensia Sicor and Sonus for which Sonus and Gensia Sicor would be considered joint authors under the United States Copyright Act or joint inventors under the United States Patent Act. Neither party may unilaterally license or assign any jointly developed Improvements without the written consent of the other party, unless the other party is compensated through a royalty, one-time payment or otherwise in an amount equal to the relative value of such party's contribution to the
- 11.4 GENSIA SICOR PRODUCT IMPROVEMENTS. Notwithstanding the provisions of Section 11.1 herein, any developments, inventions or discoveries developed or acquired solely by Gensia Sicor during the term of this Agreement which are applicable to the Product ("Gensia Sicor Product Improvements") shall be owned by Gensia Sicor, to the extent that such improvements are not covered by existing Sonus patents, patent applications, know-how or trade secrets. Sonus shall have a non-exclusive, royalty-free perpetual license to such Improvements

relating solely to the Product, whether such Improvements are patentable, patented, or kept by Gensia Sicor as proprietary know-how or trade secret, provided that such Improvements do not [\star]. In the event a Gensia Sicor Improvement [\star], Gensia Sicor shall negotiate in good faith with Sonus the terms of a license to all or any such Gensia Sicor Product Improvements

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 * Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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12. RIGHT OF FIRST NEGOTIATION.

In the event that Sonus licenses the right to develop, market and distribute the Product to a third party who is not an Affiliate of Sonus, and such licensee desires to transfer the manufacturing of the Product to a manufacturer other than Gensia Sicor, Sonus, such licensee and Gensia Sicor shall enter into a [*] period of exclusive negotiation (the "Right of First Negotiation Period") for Gensia Sicor to retain the rights to manufacture the Product for such third party. If the parties fail to come to an agreement during such Right of First Negotiation Period, Sonus and such third party shall have the right to terminate this Agreement upon six (6) months' written notice to Gensia Sicor, and transfer the manufacturing of the Product to one or more third parties, provided that the terms under which such third party manufactures the Product for Sonus's licensee shall be no less favorable to Sonus' licensee than the terms of Gensia Sicor's final offer.

13. FORCE MAJEURE.

Any delay in the performance of any of the duties or obligations of either party hereto (except the payment of money) shall not be considered a breach of this Agreement and the time required for performance shall be extended for a period equal to the period of such delay, provided that such delay has been caused by or is the result of any acts of God; insurrections; riots; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; floods; shortages in transportation, or inability to obtain necessary labor, materials, equipment, or laboratory facilities from usual sources; or other unforeseeable causes beyond the control, and provided, further, that the delay is not due to the fault or negligence of the party so affected. The party so affected shall give prompt notice to the other party of such cause and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible.

 \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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14. NOTICES.

All notices hereunder shall be delivered personally or by registered or certified mail, postage prepaid, to the following addresses of the respective parties:

Gensia Sicor Pharmaceutical Sales, Inc. 19 Hughes Irvine, California 92618-1902 Attention: President

With copy to: SICOR Inc.
19 Hughes

Irvine, California 92618-1902 Attention: General Counsel

Sonus Pharmaceuticals, Inc. 22026 20th Avenue S.E. Bothell, Washington 98021

Attention: Michael A. Martino, President and CEO

With copy to: K. C. Schaaf, Esquire
Stradling, Yocca, Carlson & Rauth
660 Newport Center Drive, Suite 1

Stradling, Yocca, Carlson & Rauth 660 Newport Center Drive, Suite 1600 Newport Beach, California 92660

Notices shall be effective upon receipt if personally delivered, or on the third business day following the date of mailing. A party may change its address listed above by notice to the other party.

15. APPLICABLE LAW.

This Agreement shall be construed, interpreted and governed by the laws of the State of California, except for choice of law rules.

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16. ASSIGNMENT.

Neither party shall assign this Agreement or any part thereof without the prior written consent of the other party, which consent shall not be unreasonably withheld; provided, however, (i) either party may assign this Agreement without consent to an Affiliate of that party, or (ii) either party may assign or sell the same without such consent in connection with the transfer or sale of substantially its entire business to which this Agreement pertains or in the event of its merger or consolidation with another company. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve any party of responsibility for the performance of any accrued obligation which such party then has hereunder.

17. ENTIRE AGREEMENT.

This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes all written or oral prior agreements or understandings with respect thereto. No course of dealing or usage of trade shall be used to modify the terms and conditions hereof.

18. SEVERABILITY.

This Agreement is subject to the restrictions, limitations, terms and conditions of all applicable laws, governmental regulations, approvals and clearances. If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

19. WAIVER - MODIFICATION OF AGREEMENT.

No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of both parties. Failure by either party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20. INDEPENDENT CONTRACTOR.

Each party shall be and shall endeavor to act as the independent contractor of the other party. Neither party shall be the legal agent of the other party for any purpose whatsoever and therefore has no right or authority to make or underwrite any promise, warranty or representation, to execute any contract or otherwise to assume any obligation or responsibility in the name or on behalf of the other party, except to the extent specifically authorized in writing by the other party, neither of the parties hereto shall be bound by or liable to any third persons for any act or any obligation or debt incurred by the other towards such third party, except for the extent specifically agreed to in writing by the party so to be bound.

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21. DISPUTE RESOLUTION; ARBITRATION.

The parties shall initially attempt in good faith to resolve any significant controversy, claim, allegation, and breach or dispute arising out of or relating to this Agreement (hereinafter collectively referred to a "Dispute") through negotiations between senior executives of Sonus and Gensia Sicor. If the Dispute is not resolved within thirty (30) days, (or such other period of time mutually agreed upon by the parties), of notice of the dispute (the "Executive Resolution Period"), then the parties agree to submit the Dispute to arbitration as provided herein. Unless otherwise mutually agreed by the parties, only if the Dispute is not resolved through negotiations as set forth herein, any party may resort to arbitration.

All Disputes relating in any way to this Agreement shall be resolved exclusively through arbitration in accordance with the commercial arbitration rules of the American Arbitration Association in then in effect. In the event either party demands arbitration, it shall do so within thirty (30) days after the expiration of the Executive Resolution (or any mutually agreed extension) and shall include a request that such arbitration be held within thirty (30) days of such demand. The arbitration hearing shall be held as soon as

practicable. The arbitration hearing shall be held in Orange County, California and shall be before a single arbitrator selected by the parties in accordance with the commercial arbitration rules of the American Arbitration Association pursuant to its rules on selection of arbitrators. The arbitrator shall render a formal, binding, non-appealable resolution and award on each issues as expeditiously as possible, but not more then ten (10) business days after the hearing. In any arbitration, the prevailing party shall be entitled to reimbursement of its reasonable attorneys fees, costs and expenses incurred in connection with the arbitration, and the parties shall use their reasonable efforts to minimize arbitration costs.

The parties, intending to be bound by the terms and conditions hereof, have caused this Agreement to be signed by their duly authorized representatives on the date first above written.

GENSIA SICOR PHARMACEUTICAL SALES, INC.

SONUS PHARMACEUTICALS, INC.

Name

By: /s/ Armand J. LeBlanc _____ By: /s/ Michael A. Martino _____

Armand J. LeBlanc

Michael A. Martino Name:

Title: President

Title: President and CEO

Date: June 26, 2002

Date: June 26, 2002

27 EXHIBIT A

API AND EXCIPIENTS SPECIFICATIONS

1. [*]

2. [*]

 \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

EXHIBIT B

PRODUCT DESCRIPTION AND SPECIFICATIONS

1. [*]

2. [*]

 \star Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

EXHIBIT C

MANUFACTURING EQUIPMENT

The following estimate details the parts and equipment to be procured by Gensia Sicor on behalf of Sonus for the manufacture of the Product.

* Omitted pursuant to Rule 24b-2 and filed separately with the Commission.
EXHIBIT D
TECHNOLOGY TRANSFER
The following estimate details those costs and services required to support the transfer of the finished product technology of Sonus for the Product.
[*]
* Omitted pursuant to Rule 24b-2 and filed separately with the Commission.
EXHIBIT E
PRE-COMMERCIAL SERVICES
The following estimate details those costs and services to be provided by Gensia Sicor to support the validation and commercialization of the Product manufacturing process.
*]
* Omitted pursuant to Rule 24b-2 and filed separately with the Commission.
EXHIBIT F
SCHEDULE
The following schedule details critical path items in the manufacturing scale-up process to meet the goal of completing manufacture of the first clinical batch of S-8184 at Gensia Sicor by end of year 2002. The project teams will together detail and agree on a project schedule for execution of the work specified in this agreement.
*]
* Omitted pursuant to Rule 24b-2 and filed separately with the Commission.
EXHIBIT G
ADDITIONAL SUPPORT SERVICES
[*]

 * Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

EXHIBIT H

\star Omitted pursuant to Rule 24b-2 and filed separately with the Commission
EXHIBIT I
MANUFACTURING AND QUALITY CONTROL PROCESSES AND PROCEDURES
[*]
* Omitted pursuant to Rule 24b-2 and filed separately with the Commission
EXHIBIT J
PRICING FOR COMMERCIAL SUPPLIES [*]

 * Omitted pursuant to Rule 24b-2 and filed separately with the Commission.

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

- I, Michael A. Martino, President and Chief Executive Officer of Sonus Pharmaceuticals, Inc. (the "Company"), certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:
- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2002 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Dated: August 13, 2002

/s/ Michael A. Martino

Michael A. Martino

President and Chief Executive Officer

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

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

- (1) the Quarterly Report on Form 10-Q of the Company for the quarterly period ended June 30, 2002 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 780(d)); and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Dated: August 13, 2002