SECURITIES AND EXCHANGE COMMISSION

# **FORM 10-Q**

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **1996-11-14** | Period of Report: **1996-09-30** SEC Accession No. 0000891020-96-001439

(HTML Version on secdatabase.com)

# **FILER**

# SONUS PHARMACEUTICALS INC

CIK:949858| IRS No.: 954343413 | State of Incorp.:DE | Fiscal Year End: 1231 Type: 10-Q | Act: 34 | File No.: 000-21243 | Film No.: 96664166 SIC: 2835 In vitro & in vivo diagnostic substances Mailing Address 22026 20TH AVENUE SE, SUITE 102 BOTHELL WA 98021 Business Address 22026 20TH AVE SE STE 102 BOTHELL WA 98021 2064879500

#### U.S. SECURITIES AND EXCHANGE COMMISSION Washington D.C. 20549 FORM 10-Q

(Mark One)

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- /X/ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 1996
- / / TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM \_\_\_\_\_\_ TO

Commission file number 0-26866

SONUS PHARMACEUTICALS, INC. (Exact Name of Registrant as Specified in Its Charter)

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

> 22026 20th Ave. S.E., Suite 102 Bothell, Washington 98021 (Address of Principal Executive Offices)

(206) 487-9500 (Registrant's Telephone Number, Including Area Code)

NOT APPLICABLE (Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Indicate by check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES X NO

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

Class

Outstanding at October 31, 1996

Common Stock, \$.001 par value

8,521,210

Page Number

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SONUS PHARMACEUTICALS, INC.

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</TABLE>

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#### SONUS PHARMACEUTICALS, INC.

#### BALANCE SHEETS

<TABLE> <CAPTION>

<caption></caption>		
	SEPTEMBER 30, 1996 (UNAUDITED)	DECEMBER 31, 1995
<s></s>	<c></c>	<c></c>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 5,926,151	\$ 5,656,620
Marketable securities	16,125,319	12,564,513
Prepaid expenses and other current assets	334,313	137,153
Total current assets	22,385,783	18,358,286
Equipment, furniture, and leasehold improvements net of accumulated		
depreciation of \$1,102,383 and \$794,364	1,074,259	1,123,089
Other assets	73,338	164,755
Total assets	\$ 23,533,380	\$ 19,646,130
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:		
Bank line of credit	\$ 5,000,000	\$ 5,000,000
Accounts payable and accrued expenses	2,304,163	1,454,607
Accrued clinical trials expenses	1,506,352	1,568,992
Current portion of capitalized lease obligations	179,854	207,247
Total current liabilities	8,990,369	8,230,846
Capitalized lease obligations, less current portion	333,326	467,989
Commitments		
Stockholders' equity:		
Preferred stock, \$.001 par value: 5,000,000 authorized; no shares		
outstanding		
Common stock, \$.001 par value: 20,000,000 shares authorized;		
8,515,724 and 8,448,082 shares outstanding in 1996 and 1995,		
respectively	34,249,811	30,106,638
Accumulated deficit	(19,986,629)	(19,066,414)
Deferred compensation	(53,497)	(92,929)
Total stockholders' equity	14,209,685	10,947,295
Total liabilities and stockholders' equity	\$ 23,533,380	\$ 19,646,130
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</TABLE>

See accompanying notes.

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SONUS PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS (UNAUDITED)

<TABLE>

<caption></caption>	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	1996	1995	1996	1995
<s></s>	<c></c>	<c></c>	<c></c>	<c></c>
Revenues:				
Collaborative agreements Operating expenses:	\$ 6,400,000	\$ 400,000	\$ 11,200,000	\$ 4,100,000
Research and development	2,495,893	1,514,081	9,380,292	4,202,548
General and administrative	923,611	524,160	2,659,356	1,651,238
	3,419,504		12,039,648	5,853,786
Operating income (loss) Other income (expense):		(1,638,241)	(839,648)	(1,753,786)
Interest income	204,711	5,669	506,768	59,036
Interest expense		(273,758)	(172,157)	(651,763)
Income (loss) before income taxes		(1,906,331)	(505,037)	(2,346,513)
Income tax expense	340,000	40,844	420,000	491,644
Net income (loss)	\$ 2,801,745	\$ (1,947,175)	\$ (925,037)	\$ (2,838,157)
Net income (loss) per share	\$ 0.31	\$ (0.95)	\$ (0.11)	\$ (1.38)
Shares used in computation of net income				
(loss) per share	9,130,992	2,050,060	8,467,100	2,061,573
Pro forma, assuming conversions into common stock:		¢ (0.05)		<u> </u>
Net loss per share		\$ (0.35) =======		\$ (0.49)
Shares used in computation of net loss				
per share		5,412,385		5,400,748

</TABLE>

See accompanying notes.

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SONUS PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS (UNAUDITED)

<TABLE> <CAPTION>

	NINE MONTHS ENDED SEPTEMBER 30,	
	1996	1995
<\$>	<c></c>	<c></c>
OPERATING ACTIVITIES		
Net loss	\$ (925,037)	\$(2,838,157)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	308,019	256,909
Amortization of premium (discount) on marketable securities	32,541	14,154
Amortization of deferred compensation	39,432	
Loss on asset retirements		66,403
Deferred taxes Changes in operating assets and liabilities:		200,000
Prepaid expenses and other assets	(105,743)	(329,184)
Accounts payable and accrued expenses	852,918	1,359,164
Change in accrued clinical trials expenses	(62,639)	326,304
Accrued relocation expenses	(3,361)	(338,680)
Deferred revenue		(400,000)
Net cash provided by (used in) operating activities		
INVESTING ACTIVITIES		
Purchases of equipment, furniture, and leasehold improvements	(259,190)	(271,453)
Purchases of marketable securities	(56,969,288)	(7,968,976)
Proceeds from sale of marketable securities	50,484,820	
Proceeds from maturities of marketable securities	2,895,942	493,087
Net cash provided by investing activities	(3,847,716)	1,275,315

FINANCING ACTIVITIES		
Proceeds from line of credit borrowings	16,400,000	3,850,000
Repayment of line of credit borrowings	16,400,000	
Repayment of notes payable to stockholders		(2,927,005)
Proceeds from capitalized lease obligations		117,171
Repayment of capitalized lease obligations	(162,057)	(212,813)
Proceeds from issuance (repurchase) of common stock and warrants	4,143,173	(25,414)
Net cash provided by financing activities	3,981,116	801,939
Increase in cash and cash equivalents for the period	269,530	394,167
Cash and cash equivalents at beginning of period	5,656,621	34,719
Cash and cash equivalents at end of period	\$ 5,926,151	\$ 428,886
	=========	=========
Supplemental cash flow information:		
Interest paid	\$ 30,962	\$ 294,381
Income taxes paid	\$ 420,000	\$ 291,644

</TABLE>

See accompanying notes

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#### SONUS PHARMACEUTICALS, INC. NOTES TO FINANCIAL STATEMENTS

#### SEPTEMBER 30, 1996 (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 accruals) 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 1995 Annual Report and incorporated by reference in Form 10-K for the year ended December 31, 1995.

#### (2) COLLABORATIVE AGREEMENTS

In May 1996, the Company formed a strategic alliance with Abbott Laboratories for the marketing and sale of EchoGen (R) Emulsion ("EchoGen") in the United States. SONUS has primary responsibility for clinical development, regulatory affairs, and medical and technical marketing support of EchoGen, and Abbott has primary responsibility for United States marketing and sales. SONUS has retained certain co-promotion rights to EchoGen in the United States. Under the agreement, Abbott has paid the Company \$7.0 million as of September 30, 1996 and has agreed to pay an additional \$24.0 million consisting of \$6.0 million in the form of quarterly payments over the next 6 quarters and \$18.0 million in the form of milestone payments conditioned on the achievement of certain regulatory and commercialization milestones. After the United States Food and Drug Administration ("FDA") has approved the marketing of EchoGen, for which there can be no assurance, SONUS will receive 47 percent of net EchoGen revenues in the United States -- a portion of which SONUS must use to fund its responsibilities under the agreement. The agreement spans the life of the patents relating to EchoGen. Abbott can acquire the rights to additional indications for EchoGen by making additional clinical support payments. In addition, Abbott purchased for \$4.0 million, five year warrants to acquire 500,000 shares of the Company's common stock at an exercise price of \$16.00 per share.

#### (3) SUBSEQUENT EVENTS

In October 1996, the Company expanded its strategic alliance with Abbott Laboratories by signing a second agreement for EchoGen that extends Abbott's licensed territory to include the following: Europe, Latin America, Canada, Middle East, Africa and certain Asia/Pacific Rim countries. Under the agreement, Abbott has agreed to pay the Company \$34.6 million in payments conditioned upon the achievement of certain regulatory and commercialization milestones, of which \$12.6 million are offsettable against future royalty payments. After applicable regulatory agencies have approved the marketing of EchoGen, for which there can be no assurance, SONUS will receive a royalty that ranges from 36% to 42% of EchoGen net sales based on aggregate annual sales in the territory. The agreement spans the life of the patents relating to EchoGen in the countries of the territory.

7 ITEM 2.

#### MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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#### OVERVIEW

Since its inception in October 1991, the Company has engaged primarily in the research and development of proprietary contrast agents for use in ultrasound imaging. The Company has financed its research and development and clinical trials through payments received under agreements with its collaborative partners, private equity and debt financings, and an initial public offering completed in 1995. As of September 30, 1996, the Company had accumulated net losses of approximately \$20.0 million since its inception. Clinical trials of the Company's principal product under development, EchoGen(R) Emulsion, began in January 1994. The Company has completed various Phase 1, Phase 2 and Phase 3 clinical trials of EchoGen since 1994 and in August 1996 submitted a new drug application ("NDA") with the FDA. The Company expects to file for marketing authorization with the European Medicines Evaluation Agency for EchoGen by year end.

The Company will not be able to commence U.S. sales of EchoGen unless and until it receives FDA approval. To date, all of the Company's revenues have been derived from option and license payments that have been received under agreements with Abbott Laboratories, Inc. ("Abbott"), Daiichi Pharmaceutical Co. Ltd. ("Daiichi"), and Guerbet S.A. for the collaborative development of EchoGen within the United States and in certain foreign territories. In May 1996, the Company formed a strategic alliance with Abbott Laboratories for the marketing and sale of EchoGen in the United States. Under the agreement, Abbott has agreed to pay the Company \$31.0 million in upfront, clinical support and milestone payments, of which \$7.0 million has been paid as of September 30, 1996. In addition, Abbott has purchased, for \$4.0 million, warrants to acquire 500,000 shares of common stock of the Company, equal to approximately six percent (6%) of the Company's outstanding common stock. The warrants are exercisable over five years at \$16.00 per share. In April 1993, the Company granted Daiichi an option to acquire exclusive marketing and distribution rights to EchoGen in certain countries in the Pacific Rim. In March 1995, Daiichi exercised the option and entered into a license agreement with the Company. Under the option and license agreements, Daiichi has paid the Company option and license fees totaling \$12.0 million and has agreed to pay an additional \$20.0 million, consisting of \$0.8 million in the form of quarterly payments over the next two quarters and \$19.2 million in the form of milestone payments conditioned on the achievement of certain clinical development, regulatory and commercialization milestones in Japan. In addition to the option and license agreements, Daiichi entered into a convertible subordinated debenture purchase agreement with the Company in November 1993 under which the Company issued a convertible subordinated debenture to Daiichi in the principal amount of \$3.0 million, which was converted into 462,857 shares of common stock concurrently with the closing of the Company's initial public offering. In October 1994, the Company granted Guerbet an option, which expired September 30, 1996, to acquire exclusive marketing and distribution rights to EchoGen in Europe. In exchange for such option, the Company received payments totaling approximately \$4.7 million, of which \$3.6 million, plus accrued interest (\$245,875 at the time of conversion), was converted into 549,410 shares of common stock of the Company concurrently with the closing of the Company's initial public offering. The remaining \$1.1 million was recognized as revenue in 1994.

The Company's results of operations have varied and will continue to vary significantly from quarter to quarter and depend on, among other factors, the timing of fees and milestone payments made by collaborative partners, the entering into product license agreements by the Company and the timing and costs of the clinical trials conducted by the Company. The Company's current collaborative partners can terminate their agreements on short notice, and there can be no assurance that the Company will receive any additional funding or milestone payments.

#### RESULTS OF OPERATIONS

Revenue from collaborative agreements increased to 6.4 million for the three months ended September 30, 1996 as compared to 400,000 for the three

months ended September 30, 1995. The revenue in the current period represents regular quarterly payments from Abbott and Daiichi as well as milestone payments related to the NDA submission with the U.S. FDA and certain Phase 2 clinical trial results. The prior period revenue represented a regular quarterly payment under the Daiichi agreement. Revenue from collaborative agreements increased to \$11.2 million for the nine months ended September 30, 1995.

Research and development expenses increased to \$2.5 million for the three months ended September 30, 1996 from \$1.5 million for the three months ended September 30, 1995 and to \$9.4 million for the nine months ended

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8 September 30, 1996 from \$4.2 million for the nine months ended September 30, 1995. The increases in the current year periods were primarily due to expenses relating to two Phase 3 clinical trials of EchoGen as well as costs incurred in the preparation and subsequent submission of the NDA.

General and administrative expenses increased to \$924,000 for the three months ended September 30, 1996 from \$524,000 for the three months ended September 30, 1995 and to \$2.7 million for the nine months ended September 30, 1996 as compared to \$1.7 million for the nine months ended September 30, 1995. The increases in the current year periods reflected increased costs of filing and prosecuting patent and trademark applications, the implementation of market research programs, legal fees related to corporate alliances, as well as investor related and other expenses resulting from being a public company.

Interest income increased to \$205,000 and \$507,000 for the three and nine months ended September 30, 1996 as compared to \$6,000 and \$59,000 for the three and nine months ended September 30, 1995, respectively, as a result of larger average invested cash balances resulting from the initial public offering and the Abbott strategic alliance. Interest expense decreased by \$230,000 and \$480,000 for the three and nine months periods ended September 30, 1996, respectively, primarily due to the repayment of notes to stockholders and the conversion of debts into common stock upon completion of the initial public offering.

Income taxes of \$340,000 and \$41,000 for the three months ended September 30, 1996 and 1995, respectively, and income taxes of \$420,000 and \$492,000 for the nine months ended September 30, 1996 and 1995, respectively, were primarily attributable to withholding taxes paid to Japan relating to the collaborative payments received from Daiichi.

#### LIQUIDITY AND CAPITAL RESOURCES

Through September 30, 1996, the Company has financed its operations with payments from Abbott, Daiichi and Guerbet of \$26.7 million, proceeds from the issuance of convertible, redeemable preferred stock of \$4.0 million (which converted into common stock at the closing of the Company's initial public offering), proceeds from a line of credit of \$5.0 million, net proceeds of \$19.0 million from the initial public offering and proceeds of \$4.0 million for the issuance of Common Stock warrants. At September 30, 1996, the Company had cash, cash equivalents and marketable securities of \$22.1 million, compared to \$18.2 million at December 31, 1995. Cash provided by operations for the nine months ended September 30, 1996 was \$136,000 as compared to cash used in operations of \$1.7 million for the nine months ended September 30, 1995.

In August 1996, the Company renewed a loan agreement with Silicon Valley Bank which provides for a \$5.0 million revolving line of credit facility, which is secured by the tangible assets of the Company. At September 30, 1996, there was \$5.0 million outstanding under the line of credit. The line of credit expires in August 1997 and bears interest at the prime rate plus 1.0% per annum and the Company is required to maintain certain minimum balances of cash, cash equivalents and marketable securities.

The Company's cash needs may increase in future periods due to its pending and planned research and clinical development programs. The Company estimates that existing cash, cash equivalents and marketable securities will be sufficient to meet the Company's capital requirements for at least the next 12 months. The Company's future capital requirements will, however, depend on many factors, including the progress of the Company's research and development programs, clinical trials, the time and costs required to gain regulatory approvals, the ability of the Company to obtain and retain continued funding from third parties under collaborative agreements, the costs of filing, prosecuting and enforcing patents, patent applications, patent claims and trademarks, the costs of marketing and distribution, the status of competing products and the market acceptance of the Company's products, if and when approved. The Company may have to raise substantial additional funds to complete development of any product or to commercialize any products if and when approved by the FDA. There can be no assurance that additional financing will be available on acceptable terms, if at all.

#### FORWARD-LOOKING STATEMENTS

This 10-Q report contains certain forward-looking statements that involve risk and uncertainties. As discussed in the Company's 1995 annual report on Form 10-K, the Company's future operating results are uncertain and may be impacted by the following factors, among others: FDA and foreign regulatory requirements, lengthy regulatory approval process, uncertainty of clinical trials for additional clinical indications of EchoGen, future capital requirements and

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uncertainty of additional funding, dependence on third parties for funding, clinical development and distribution and uncertainty of market acceptance.

#### PART II. OTHER INFORMATION

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ITEM 4. EXHIBITS AND REPORTS ON FORM 8-K

(A) EXHIBITS

Number Description

- Computation of net income (loss) per share.
   Computation of pro forma net income (loss) per share.
- (B) REPORTS ON FORM 8-K

The Company filed the following report on Form 8-K during the quarter ended June 30, 1996:

1. The Registrant filed a report on Form 8-K on August 23, 1996 in connection with the adoption of a Shareholder Rights Plan dated July 29, 1996.

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10 SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

By:

#### SONUS PHARMACEUTICALS, INC.

Date: November 14, 1996

/s/ Gregory Sessler Gregory Sessler Chief Financial Officer and Assistant Secretary (Principal Financial Officer and Duly Authorized Officer)

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EXHIBIT INDEX

Exhibit Number 	Description	Page Number
11.1	Computation of net income (loss) per share	12
11.2	Computation of pro forma net income (loss) per share	13

# SONUS PHARMACEUTICALS, INC.

# COMPUTATION OF NET INCOME (LOSS) PER SHARE

<TABLE> <CAPTION>

	Three Months Ended September 30,		Nine Months Ended September 30,		
	1996	1995	1996	1995	
<s> Net income (loss)</s>	<c> \$2,801,745</c>	<c> \$(1,947,175)</c>	<c> \$ (925,037)</c>	<c> \$(2,838,157)</c>	
Weighted average shares outstanding Net effect of stock option exercised and stock options and warrants granted during the 12 months prior to the Company's filing of its initial public offering, calculated using the treasury stock method at the offering price of \$7 per share, and treated as outstanding for all periods prior to the closing of the initial public offering	8,490,201	1,952,864 97,196	8,467,100	1,963,843 97,730	
Net effect of common stock equivalents calculated using the treasury stock method	640,790				
Shares used in computation of net income (loss) per share	9,130,992	2,050,060	8,467,100	2,061,573	
Net income (loss) per share	\$ 0.31 ========	\$ (0.95)	\$ (0.11)	\$ (1.38)	

  |  |  |  |12

# EXHIBIT 11.2

# SONUS PHARMACEUTICALS, INC.

# COMPUTATION OF PRO FORMA NET INCOME (LOSS) PER SHARE

#### <TABLE> <CAPTION>

<caption></caption>	Three Months Ended September 30, 1995	Nine Months Ended September 30, 1995
<s> Net loss Add interest on deferred revenue</s>	<c> \$(1,947,175) 76,412</c>	<c> \$(2,838,157) 204,913</c>
	\$(1,870,763)	\$(2,633,244)
Weighted average shares outstanding Weighted average common shares giving effect to the	========= 1,952,864	1,963,843
conversion of preferred stock into common stock for all periods subsequent to issuance Net effect of stock options exercised and stock options and warrants granted during the 12 months prior to the Company's filing of its	2,352,219	2,352,219
<pre>initial public offering calculated using the treasury stock method at the offering price of \$7 per share, and treated as outstanding for all periods prior to the closing of the initial public offering Weighted average common shares giving effect to the conversion of the convertible subordinated debenture</pre>	97,196	97,730
<pre>into common stock using the initial public offering price of \$7 per share Weighted average common shares giving effect to the conversion of \$3.6 million of deferred revenue from</pre>	462,857	462,857
the time of receipt, plus accrued interest at the initial public offering price of \$7 per share	547,249	524,099
Shares used in computation of pro forma net loss per share	5,412,385	5,400,748
Pro forma net loss per share	======================================	============ \$ (0.49) =========

</TABLE>

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