

SECURITIES AND EXCHANGE COMMISSION

FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

Filing Date: **2003-02-10** | Period of Report: **2002-12-31**

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FILER

OSI PHARMACEUTICALS INC

CIK: **729922** | IRS No.: **133159796** | State of Incorporation: **DE** | Fiscal Year End: **0930**

Type: **10-Q** | Act: **34** | File No.: **000-15190** | Film No.: **03545657**

SIC: **2835** In vitro & in vivo diagnostic substances

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934For the quarterly period ended December 31, 2002 .

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934For the transition period from _____ to _____ .
-----Commission file number 0-15190
-----OSI Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware 13-3159796
-----(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)58 South Service Road, Suite 110, Melville, New York 11747

(Address of principal executive offices) (Zip Code)

631-962-2000

(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since
last report.)Indicate by check mark whether the registrant (1) has filed all reports required
to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during
the preceding 12 months (or for such shorter period that the registrant was
required to file such reports), and (2) has been subject to such filing
requirements for the past 90 days. Yes X No
--- ---Indicate by check mark whether the registrant is an accelerated filer (as
defined in Rule 12b-2 of the Exchange Act). Yes X No
--- ---

APPLICABLE ONLY TO CORPORATE ISSUERS:

At January 31, 2003 the registrant had outstanding 36,444,636 shares of common
stock, \$.01 par value.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONTENTS

<TABLE>
<CAPTION>

<S>

PAGE NO.

<C>

PART I. FINANCIAL INFORMATION.....	1
Item 1. Financial Statements.....	1
Consolidated Balance Sheets	
- December 31, 2002 (unaudited) and September 30, 2002.....	1
Consolidated Statements of Operations	
- Three Months Ended December 31, 2002 and 2001 (unaudited).....	2
Consolidated Statements of Cash Flows	
- Three Months Ended December 31, 2002 and 2001 (unaudited).....	3
Notes to Consolidated Financial Statements.....	4
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.....	10
Item 3. Quantitative and Qualitative Disclosures About Market Risk.....	21
Item 4. Controls and Procedures.....	22
PART II. OTHER INFORMATION.....	24
Item 1. Legal Proceedings.....	24
Item 2. Changes in Securities and Use of Proceeds.....	24
Item 3. Defaults Upon Senior Securities.....	24
Item 4. Submission of Matters to a Vote of Security Holders.....	24
Item 5. Other Information.....	24
Item 6. Exhibits and Reports on Form 8-K.....	24
SIGNATURES.....	26
CERTIFICATIONS.....	27
EXHIBIT INDEX.....	31

</TABLE>

i

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

<TABLE>

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	DECEMBER 31, 2002	SEPTEMBER 30, 2002
	-----	-----
	(UNAUDITED)	
<S>	<C>	<C>
ASSETS		
Current assets:		
Cash and cash equivalents.....	\$ 121,810	\$ 152,578
Investment securities.....	308,582	304,388
Restricted investment securities - short-term.....	3,968	7,938
Receivables, including amounts due from related parties of \$1,209 and \$3,000 at December 31, 2002 and September 30, 2002, respectively.....	1,284	3,253
Interest receivable.....	3,669	3,728
Prepaid expenses and other current assets.....	4,282	3,873
	-----	-----
Total current assets.....	443,595	475,758
	-----	-----
Restricted investment securities - long-term.....	11,468	11,373
Property, equipment and leasehold improvements - net.....	44,939	46,175
Debt issuance costs - net.....	4,942	5,145
Goodwill.....	38,739	38,648
Other assets.....	1,954	1,945
	-----	-----

	\$ 545,637	\$ 579,044
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses, including amounts due to related parties of \$2,392 and \$2,190 at December 31, 2002 and September 30, 2002, respectively.....	\$ 21,516	\$ 22,062
Unearned revenue - current; including amounts received in advance from related parties of \$5,677 and \$7,687 as of December 31, 2002 and September 30, 2002, respectively.....	6,444	8,613
Loans payable - current.....	422	527
	-----	-----
Total current liabilities.....	28,382	31,202
	-----	-----
Other liabilities:		
Unearned revenue - long-term; representing amounts received in advance from related parties.....	5,000	6,250
Convertible senior subordinated notes and loans payable-long-term.....	160,000	160,014
Accrued postretirement benefit cost.....	2,644	2,470
	-----	-----
Total liabilities.....	196,026	199,936
	-----	-----
Stockholders' equity:		
Preferred stock, \$.01 par value; 5,000 shares authorized; no shares issued at December 31, 2002 and September 30, 2002.....	--	--
Common stock, \$.01 par value; 200,000 shares authorized, 37,376 and 37,335 shares issued at December 31, 2002 and September 30, 2002, respectively.....	374	373
Additional paid-in capital.....	708,761	708,435
Deferred compensation.....	(18)	(49)
Accumulated deficit.....	(354,323)	(324,223)
Accumulated other comprehensive income.....	1,250	1,005
	-----	-----
	356,044	385,541
Less: treasury stock, at cost; 940 shares at December 31, 2002 and September 30, 2002.....	(6,433)	(6,433)
	-----	-----
Total stockholders' equity.....	349,611	379,108
	-----	-----
Commitments and contingencies		
	\$ 545,637	\$ 579,044
	=====	=====

</TABLE>

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)
(IN THOUSANDS EXCEPT PER SHARE DATA)

		THREE MONTHS ENDED DECEMBER 31	
		2002	2001
		-----	-----
		<C>	<C>
<S>			
Revenues:			
Collaborative program revenues, including \$2,010 and \$2,257 from related parties in 2002 and 2001, respectively.....	\$	2,982	\$ 3,116
License and other revenues, including \$1,250 and \$2,083 from related parties in 2002 and 2001, respectively.....		1,490	2,776
		-----	-----
		4,472	5,892
		-----	-----
Expenses:			

Research and development.....	28,223	17,254
Acquired in-process research and development (see note 3).....	--	130,200
Selling, general and administrative.....	7,500	5,856
Amortization of intangibles.....	54	309
	-----	-----
	35,777	153,619
	-----	-----
Loss from operations.....	(31,305)	(147,727)
Other income (expense):		
Investment income - net.....	2,669	4,574
Interest expense.....	(1,607)	(2)
Other income - net.....	143	773
	-----	-----
Net loss.....	\$ (30,100)	\$ (142,382)
	=====	=====
Weighted average shares of common stock outstanding.....	36,414	35,140
	=====	=====
Basic and diluted net loss per common share.....	\$ (0.83)	\$ (4.05)
	=====	=====

</TABLE>

See accompanying notes to consolidated financial statements.

2

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(IN THOUSANDS)

<TABLE>
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	THREE MONTHS ENDED DECEMBER 31	
	2002	2001
	-----	-----
<S>	<C>	<C>
Cash flow from operating activities:		
Net loss.....	\$ (30,100)	\$ (142,382)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of diagnostic business.....	--	(1,000)
Loss (gain) on sale of investments.....	(345)	269
Depreciation and amortization.....	3,015	1,950
In-process research and development charge on acquisition of Gilead's oncology assets.....	--	130,200
Non-cash compensation charges.....	101	1,887
Changes in assets and liabilities, net of the effects of business acquisition in 2001:		
Receivables.....	2,029	(228)
Prepaid expenses and other current assets.....	(352)	(610)
Other assets.....	25	(66)
Accounts payable and accrued expenses.....	(675)	(5,755)
Unearned revenue.....	(3,419)	(1,550)
Accrued postretirement benefit cost.....	174	75
	-----	-----
Net cash used in operating activities.....	(29,547)	(17,210)
	-----	-----
Cash flows from investing activities:		
Payments for acquisitions.....	--	(134,942)
Net proceeds from sale of diagnostic business.....	--	1,000
Purchases of investments (restricted and unrestricted).....	(127,078)	(85,624)
Maturities and sales of investments (restricted and unrestricted).....	126,658	79,540

Additions to property, equipment and leasehold improvements.....	(821)	(943)
Additions to compound library assets.....	(45)	--
Investments in privately-owned companies.....	(50)	(500)
	-----	-----
Net cash used in investing activities.....	(1,336)	(141,469)
	-----	-----
Cash flows from financing activities:		
Proceeds from exercise of stock options, stock warrants and employee purchase plan.....	256	1,582
Payments on loans and capital leases payable - net.....	(128)	(32)
	-----	-----
Net cash provided by financing activities.....	128	1,550
	-----	-----
Net decrease in cash and cash equivalents.....	(30,755)	(157,129)
Effect of exchange rate changes on cash and cash equivalents.....	(13)	(88)
Cash and cash equivalents at beginning of year.....	152,578	225,150
	-----	-----
Cash and cash equivalents at end of period.....	\$ 121,810	\$ 67,933
	=====	=====
Non-cash activities:		
Issuance of common stock to employees.....	\$ 91	\$ 375
	=====	=====
Issuance of common stock in connection with acquisition of certain assets from Gilead.....	\$ --	\$ 40,000
	=====	=====

</TABLE>

See accompanying notes to consolidated financial statements.

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(UNAUDITED)

(1) Basis of Presentation

In the opinion of management, the accompanying unaudited consolidated financial statements contain all adjustments (consisting of only normal recurring accruals) necessary to present fairly the financial position of OSI Pharmaceuticals, Inc. and its subsidiaries (the "Company") as of December 31, 2002, their results of operations for the three months ended December 31, 2002 and 2001 and their cash flows for the three months ended December 31, 2002 and 2001. Certain reclassifications have been made to the prior period financial statements to conform them to the current presentation.

It is recommended that these consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto in the Company's annual report on Form 10-K, as amended, for the fiscal year ended September 30, 2002. Results for interim periods are not necessarily indicative of results for the entire year.

(2) Revenue Recognition

The Company accounts for upfront nonrefundable technology access and other upfront fees over the term of the related research collaboration period in accordance with the guidance provided in the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements," as amended. The Company received a total of \$25.0 million in upfront fees from Genentech, Inc. and Roche in January 2001 which was being recognized on a straight-line basis evenly over the expected three-year term of the Company's required research and development efforts under the terms of the agreement. In the fourth quarter of fiscal 2002, the expected term was changed to four years to reflect the Company's revised estimate of the term of the continued involvement in the research and development efforts under the Tripartite Agreement with Genentech and Roche. In accordance with Accounting Principle Board Opinion No. 20 "Accounting Changes," the remaining deferred

revenue is being recognized prospectively over the revised term. As a result, the Company recorded revenues of \$1.3 million in the first quarter of fiscal 2003 compared to \$2.1 million had the upfront fees continued to be recognized over a three-year period. This change in estimate increased the basic and diluted loss by \$.02 per share for the three months ended December 31, 2002.

(3) Acquisition

On December 21, 2001, the Company acquired certain assets from Gilead Sciences, Inc. pursuant to the terms of an Asset Purchase Agreement dated as of November 26, 2001. The results of operations of Gilead's oncology assets have been included in the consolidated statement of operations commencing as of the date of the closing. In consideration for the assets, the Company paid approximately \$135.7 million, which includes professional fees and

4

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

the assumption of certain liabilities, and issued 924,984 shares of common stock, valued at \$40.0 million.

The acquisition was accounted for under the purchase method of accounting. The purchase price was allocated to the acquired assets and liabilities assumed based on the fair values as of the date of the acquisition. The value assigned to the acquired in-process research and development, in-process R&D, was determined by identifying those acquired in-process research projects for which: (a) technological feasibility had not been established at the acquisition date, (b) there was no alternative future use, and (c) the fair value was estimable based on reasonable assumptions. The acquired in-process R&D was valued at \$130.2 million and expensed at the acquisition date and is included in the accompanying consolidated statement of operations for the three months ended December 31, 2001.

(4) Restricted Investments Securities

With respect to the convertible senior subordinated notes, issued in February 2002, the Company originally pledged \$22.9 million of U.S. Government securities (Restricted Investment Securities) with maturities at various dates through November 2004. The aggregate amortized cost of the Restricted Investment Securities at December 31, 2002 was \$15.4 million. Included in cash and cash equivalents on the accompanying consolidated balance sheet as of December 31, 2002 is \$4.0 million relating to the Restricted Investment Securities that have reached maturity.

(5) Comprehensive Income (Loss)

Comprehensive loss for the three months ended December 31, 2002 and 2001 was as follows (in thousands):

<TABLE>
<CAPTION>

	FOR THE THREE MONTHS ENDED DECEMBER 31,	
	2002	2001
<S>	<C>	<C>
Net loss	\$ (30,100)	\$ (142,382)
Other comprehensive income (loss):		
Foreign currency translation adjustments	659	(254)
Unrealized holding loss arising during period	(66)	(899)
Less: Reclassification adjustment for losses (gains) realized in income	(348)	269
	245	(884)
Total comprehensive loss	\$ (29,855)	\$ (143,266)
	=====	=====

</TABLE>

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

The components of accumulated other comprehensive income were as follows (in thousands):

<TABLE>
<CAPTION>

	DECEMBER 31, 2002	SEPTEMBER 30, 2002
	-----	-----
<S>	<C>	<C>
Cumulative foreign currency translation adjustment.....	\$ 339	\$ (320)
Unrealized gains on available-for-sale securities.....	911	1,325
	-----	-----
Accumulated other comprehensive income	\$ 1,250	\$ 1,005
	=====	=====

</Table>

(6) Net Loss per Common Share

A reconciliation between the numerators and the denominators of the basic and diluted net loss per share computation is as follows (in thousands except per share data):

<TABLE>
<CAPTION>

	FOR THE THREE MONTHS ENDED DECEMBER 31,	
	-----	-----
	2002	2001
<S>	<C>	<C>
Net loss	\$ (30,100)	\$ (142,382)
	=====	=====
Weighted average common shares	36,414	35,140
Effect of common share equivalents	--	--
	-----	-----
Weighted average common and potential common shares outstanding	36,414	35,140
	=====	=====
Basic net loss per share	\$ (0.83)	\$ (4.05)
	=====	=====
Diluted net loss per share	\$ (0.83)	\$ (4.05)
	=====	=====

</TABLE>

Basic and diluted net loss per share is computed by dividing the net loss per share by the weighted average number of common shares outstanding during the period. The diluted net loss per share presented excludes the effect of common share equivalents (stock options and convertible debt) since such inclusion in the computation would be anti-dilutive. Such common share equivalents (options and convertible debt, assuming all shares upon conversion would be dilutive) amounted to 4.1 million for the three months ended December 31, 2002. Such common share equivalents (options) amounted to 1.8 million for the three months ended December 31, 2001.

(7) Consolidation of Facility

In the fourth quarter of fiscal 2001, the Company announced its strategic decision to close down its Birmingham, England facility. The operations at the Birmingham, England

facility ceased on March 31, 2002; however, the Company is still in the process of closing down the facility.

As of December 31, 2002, the remaining restructuring reserve relating to the consolidation of the Birmingham, England facility was \$984,000 relating to non-cancelable lease exit costs. The consolidation activity for the three months ended December 31, 2002 was as follows (in thousands):

	LEASE EXIT COSTS -----
Balance at September 30, 2002.....	\$ 1,630
Cash paid.....	(693)
Foreign currency translation adjustments.....	47

Balance at December 31, 2002.....	\$ 984
	=====

(8) Sale of Diagnostics Business

On November 30, 1999, the Company sold assets of its diagnostics business to The Bayer Corporation including the assets of the Company's wholly-owned diagnostics subsidiary, OSDI, Inc. based in Cambridge, Massachusetts. The assets sold included certain contracts, equipment and machinery, files and records, intangible assets, intellectual property, inventory, prepaid expenses and other assets primarily related to the operations of the diagnostics business. Under the terms of the sale, the Company received a contingent payment of \$1.0 million in December 2001, which is included in other income for the three months ended December 31, 2001.

(9) Accounting for Goodwill and Other Intangible Assets

Effective October 1, 2002, the Company fully adopted SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill and intangible assets determined to have indefinite lives no longer be amortized but instead be tested for impairment at least annually and whenever events or circumstances occur that indicate impairment might have occurred.

As of September 30, 2002, the Company's intangible assets were \$39.1 million, consisting of \$36.5 million of goodwill, \$2.1 million of acquired workforce, and \$458,000 for a license to compound libraries. In accordance with SFAS No. 142, the goodwill has not been amortized as it was acquired in connection with the acquisition of certain oncology assets from Gilead, which occurred after July 1, 2001. Upon full adoption of SFAS No. 142, acquired workforce no longer meets the definition of an identifiable intangible asset. As a result, the net balance of \$2.1 million as of September 30, 2002 was reclassified to goodwill. The carrying amount of goodwill as of December 31, 2002, inclusive of the acquired workforce, was \$38.7

million, which includes a \$91,000 effect from foreign currency exchange rate fluctuations during the three month period ended December 31, 2002.

The Company's identifiable intangible asset (license for compound libraries), is subject to amortization. The Company reassessed the useful lives of this intangible asset to make any necessary amortization period adjustments. No adjustments resulted from this assessment. Amortization expense for this intangible asset for the three months ended December 31, 2002 and 2001 was \$54,000 and \$53,000, respectively. Amortization expense is estimated to be \$179,000 for the remainder of fiscal 2003, \$239,000 in fiscal 2004 and \$0 in fiscal 2005.

Under the non-amortization approach, goodwill and certain other intangibles are not amortized into results of operations but instead are reviewed for impairment, written down, and charged to results of operations in periods in which the recorded value of goodwill and certain other intangibles is more than their implied fair value. The Company completed its impairment review of goodwill during the first quarter of fiscal 2003 and determined that no impairment charge was required upon adoption. A reconciliation of previously reported net loss and net loss per share to the amounts adjusted for the exclusion of acquired workforce amortization, is as follows (in thousands except per share data):

	For the three months ended December 31,	
	2002	2001
Reported net loss	\$ (30,100)	\$ (142,382)
Goodwill amortization	--	--
Acquired workforce amortization	--	258
Adjusted net loss	\$ (30,100)	\$ (142,124)
Reported basic and diluted net loss per share..	\$ (0.83)	\$ (4.05)
Goodwill amortization per share	--	--
Acquired workforce amortization per share	--	0.01
Adjusted basic and diluted net loss per share..	\$ (0.83)	\$ (4.04)

(10) Amendment to Stock Option Plan

On December 11, 2002, the Board of Directors approved an amendment to the 2001 Incentive and Non-Qualified Stock Option Plan (the "Stock Option Plan"). The amendment to the Stock Option Plan only affected the automatic, formula-based grants of non-qualified stock options to directors who are not employees of the Company. Under the amended formula, each individual who becomes a director on or after January 1, 2003 will receive an initial option to purchase 50,000 shares of common stock upon his or her election to the Board. Persons elected to the Board after June 13, 2001 but prior to January 1, 2003 were entitled to

OSI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)
(UNAUDITED)

an initial grant of an option to purchase 30,000 shares of common stock upon their initial election. All persons elected to the Board after June 13, 2001 receive grants of options to purchase 7,500 shares upon reelection to the Board. Persons elected to the Board prior to June 13, 2001, will continue to be eligible for annual grants of options to purchase shares of common stock in an amount which depends upon the number of years of service as a director (20,000 shares reducing to 7,500 shares).

(11) Amendment to the Stock Purchase Plan for the Non-Employee Directors

On December 11, 2002, the Board of Directors approved an amendment to the Company's Stock Purchase Plan for Non-Employee Directors which was adopted as of March 25, 1996 (the "Stock Purchase Plan"). Pursuant to the amended Stock Purchase Plan, fifty-percent of the annual retainer fee earned by each non-employee director will be paid to the director in the form of a restricted stock award. The restricted stock award will be made as of each annual stockholder meeting at which directors are elected beginning with the Annual Meeting of Stockholders set for March 19, 2003. Annual restricted stock awards will vest in monthly installments over the one-year term for which the award is made. In the event a director's membership on the Board terminates prior to the end of such one-year term, any unvested portion of the director's restricted stock award will be forfeited. Shares of restricted stock awarded annually may

not be sold or transferred by the director until the first anniversary of the date of grant of such award. Non-employee directors may elect to receive the remaining fifty-percent of the director's annual retainer in the form of shares of common stock under the Stock Purchase Plan as well.

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

THREE MONTHS ENDED DECEMBER 31, 2002 AND 2001

OVERVIEW

We are a leading biotechnology company focused on the discovery, development and commercialization of high-quality oncology products that both extend life and improve the quality-of-life for cancer patients worldwide. We have established a balanced pipeline of oncology drug candidates that includes both next-generation cytotoxic chemotherapy agents and novel mechanism-based, gene-targeted therapies. We currently have four proprietary candidates in clinical trials and two additional candidates in clinical trials with Pfizer Inc.

Our most advanced drug candidate, Tarceva(TM) (erlotinib HCl), is a small molecule inhibitor of the epidermal growth factor receptor, or HER1/EGFR. The protein product of the HER1/EGFR gene is a receptor tyrosine kinase that is over-expressed or mutated in many major solid tumors. We believe HER1/EGFR inhibitors represent an exciting new class of relatively safe and well tolerated anti-cancer agents that may have utility in treating a wide range of cancer patients. Tarceva(TM) is an oral once-a-day small molecule drug designed to specifically block the activity of the HER1/EGFR protein. Currently, we are developing Tarceva(TM) in an alliance with Genentech, Inc. and Roche. If the drug receives regulatory approval, Genentech will lead the marketing effort in the United States and Roche will market it in the rest of the world. We will receive milestone payments from both Genentech and Roche, an equal profit share from U.S. sales, and royalties on sales outside of the United States. Tarceva(TM) has demonstrated encouraging indications of anti-cancer activity in single-agent, open label Phase II trials in non-small cell lung cancer, head and neck cancer and ovarian cancer. Tarceva(TM) is currently in Phase III clinical trials for non-small cell lung cancer and pancreatic cancer. In January 2003, we announced the completion of patient enrollment in the Phase III refractory/advanced non-small cell lung and pancreatic cancer trials. The alliance has now completed target enrollment in all four Phase III Tarceva(TM) trials, which involves a total of approximately 3,500 patients.

Behind Tarceva(TM) we have five additional drug candidates in earlier stages of clinical development. Three of these (OSI-211, OSI-7904L and OSI-7836) are next generation cytotoxic chemotherapy agents, which are being developed by us, and the other two (CP-547,632 and CP-724,714) are gene-targeted therapies currently being developed by Pfizer. We own commercial rights to the first three and will receive royalty payments on the latter two if they are successfully commercialized.

Our next generation cytotoxic chemotherapy candidates are designed to improve upon currently marketed products in the same drug class. OSI-211 is a liposomal formulation of lurtotecan, a topoisomerase-I inhibitor, that is being developed to compete with topotecan

(Hycamptin(R)). OSI-7904L is a liposomal formulation of a thymidylate synthase inhibitor, GW 1843, that is being developed as a potential competitor to 5-Fluorouracil (5-FU) and capecitabine (Xeloda(R)), and OSI-7836 is a nucleoside analog being developed to compete with gemcitabine (Gemzar(R)). OSI-211 is in Phase II clinical trials, and OSI-7904L and OSI-7836 are in Phase I clinical trials. Like Tarceva(TM), the two gene-targeted therapies are receptor tyrosine kinase inhibitors. CP-547,632 is a small molecule targeting the vascular

endothelial growth factor receptor, or VEGFR, and CP-724,714 is a small molecule targeting HER2/erbB2. Both agents are currently in Phase I clinical trials.

In order to support our clinical pipeline, we have established (through acquisition and internal investment) a high quality oncology clinical development and regulatory affairs capability and a pilot scale chemical manufacturing and process chemistry group. Behind our clinical pipeline we have an extensive, fully integrated small molecule drug discovery organization designed to generate a pipeline of high quality oncology drug candidates to move into clinical development. This research operation has been built upon our historical strengths in high throughput screening, chemical libraries, medicinal and combinatorial chemistry, and automated drug profiling technology platforms.

With oncology as our focus, we have made the strategic decision to divest all non-oncology research programs by the end of our second quarter in fiscal 2003 or shortly thereafter, and realign our internal resources toward an oncology strategy. In July 2002, we agreed to accelerate the conclusion of the phase-down period of our funded research alliance with Anaderm Research Corporation, a wholly-owned subsidiary of Pfizer focused on the development of novel treatments for skin and hair conditions. As of December 31, 2002, we received \$4.5 million of a total \$8.0 million phase-down fee for transferring to Anaderm all of our research related to this collaboration. We will also receive royalties on the sale of products for these treatments which may arise from compounds that we have identified. We expect the transfer to be completed in the second quarter. We also plan to divest our diabetes program and certain of our adenosine receptor assets into a newly formed and externally funded entity in which we will maintain a minority interest. Our diabetes program includes a partnership with the Vanderbilt University Diabetes Center, a funded alliance with Tanabe Seiyaku Co. Ltd., and six proprietary gene-targeted discovery programs in the lead seeking and lead optimization phases, primarily focused in the glucose regulation and obesity fields. We also intend to transfer to this entity our existing diabetes teams comprised of approximately 24 employees. If we are unable to obtain external funding for this newly formed entity, we will consider other alternatives to discontinue the diabetes program, including the out-licensing of diabetes assets and employee headcount reductions.

Historically, our research organization had been established to provide early stage discovery research services to our pharmaceutical industry partners who funded these activities. Since some of our employee skill sets were from this multi-disease drug discovery service focus of our past collaborations and not ideally suited to an oncology-only strategy, in October 2002, we made the decision to reduce our employee headcount by approximately 9%

11

as we strive to better balance our staff and skill sets to focus on oncology while maintaining strong fiscal control of the business.

CRITICAL ACCOUNTING POLICIES

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States. As such, we are required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenue and expenses during the periods presented. Actual results could differ significantly from those estimates under different assumptions and conditions. We believe that the following discussion addresses our most critical accounting policies which are those that are most important to the portrayal of our financial condition and results of operations and which require our most difficult and subjective judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. Note 1 to the consolidated financial statements included in our annual report on Form 10-K as amended for the year ended September 30, 2002 includes a summary of the significant accounting policies used in the preparation of the consolidated financial statements.

Revenue Recognition

We recognize all nonrefundable upfront license fees, including upfront technology access fees, as revenue over the term of the related research collaboration period in accordance with the guidance provided in the Securities and Exchange Commission's Staff Accounting Bulletin No. 101 - "Revenue

Recognition in Financial Statements," as amended, or SAB No. 101. Our most significant application of this policy, to date, is the \$25.0 million in upfront fees received from Genentech and Roche in January 2001 which was originally being recognized evenly over the expected three-year term of our required research and development efforts under the terms of the agreement. The expected term is subject to change based upon the parties' continuous monitoring of current research data and their projections for the remaining development period. A change in this expected term impacts the period over which the remaining deferred revenue would be recognized. In the fourth quarter of fiscal 2002, the expected term was changed to four years to reflect the revised estimated timing of our research and development commitment for Tarceva(TM) under the alliance. The revision was a result of the review of the current research data available, current developments in the HER1/EGFR targeted therapy market and the involved parties' revised projections for the clinical development plan. As a result of this revision, we recorded revenues of \$1.3 million for the three months ended December 31, 2002 compared to \$2.1 million had the upfront fees continued to be recognized over a three-year period. Collaborative program revenues represent funding arrangements for research and development in the field of biotechnology and are recognized when earned in accordance with the terms of the contracts and the related development activities undertaken. Collaborative and other revenues are accrued for expenses

12

incurred in advance of the reimbursement and deferred for cash payments received in advance of expenditures. Such deferred revenues are recorded as revenue when earned.

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred to date but not yet invoiced in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ significantly from those estimates under different assumptions.

Accounting for Goodwill and Other Intangible Assets

Effective October 1, 2002, we fully adopted SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 requires that goodwill and intangible assets determined to have indefinite lives no longer be amortized but instead be tested for impairment at least annually and whenever events or circumstances occur that indicate impairment might have occurred. We reassessed the useful life of our intangible asset (license for compound libraries) to make any necessary amortization period adjustments. No adjustments resulted from this assessment. Our identifiable intangible asset is subject to amortization.

Under the non-amortization approach, goodwill and certain other intangibles are not amortized into results of operations but instead are reviewed for impairment, written down, and charged to results of operations in periods in which the recorded value of goodwill and certain other intangibles is more than their implied fair value. We completed our impairment review of goodwill during the first quarter of fiscal 2003 and determined that no impairment charge was required upon adoption.

Accounting for the Impairment of Long-Lived Assets

On October 1, 2002, we adopted the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." SFAS No. 144 requires, among other things, that long-lived assets to be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. Intangibles with determinable lives and other long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Our judgments regarding the existence of impairment indicators are based on historical and projected future operating results, changes in the manner of our use of the acquired assets or our overall business strategy, and market and economic trends. In the future, events could cause us to conclude that impairment indicators exist and that certain intangibles with determinable lives and other long-lived assets are impaired which may result in an adverse impact on our financial condition and results of

did not have an impact on our consolidated financial statements as of and for the quarter ended December 31, 2002.

REVENUES

Total revenues for the three months ended December 31, 2002 were \$4.5 million, a decrease of \$1.4 million or 24% compared to revenues of \$5.9 million for the three months ended December 31, 2001. Total collaborative program revenues of \$3.0 million for the three months ended December 31, 2002 decreased \$134,000 or 4% compared to the three months ended December 31, 2001. This decrease was primarily due to the phase-down of our collaboration with Anaderm, the conclusion of our funded collaboration with Sankyo Co., Ltd. in December 2001 and the conclusion of our service agreement with Helicon Therapeutics, Inc. in August 2002. This decrease was offset by increased revenues relating to our collaboration with Tanabe Seiyaku Co., Ltd. In July 2002, we entered into an agreement with Pfizer to accelerate the phase-down period of the collaboration with Anaderm so that it will terminate no later than April 23, 2003. In consideration for the work to be performed by us during the accelerated phase-down period, we received \$4.5 million in September 2002 and will receive \$3.5 million upon the successful completion of the transition period. The \$4.5 million is being recognized as revenue ratably over the expected term of the transition period and the \$3.5 million will be recognized upon the successful completion of the transition. As of December 31, 2002, we have recognized \$3.8 million of revenue related to the phase-down. As we continue to focus our business away from collaborative-based to independent drug discovery and development, we expect collaborative revenues to continue to decrease.

License and other revenues of \$1.5 million for the three months ended December 31, 2002 decreased \$1.3 million or 46% compared to the three months ended December 31, 2001. This decrease was due primarily to the decrease in the amount of revenue recognized relating to the \$25.0 million upfront fees received from Genentech and Roche (see note 2 to the accompanying unaudited consolidated financial statements). In accordance with the provisions of SAB No. 101, we were recognizing the \$25.0 million received from Genentech and Roche evenly over the expected three-year development phase of our agreement. In the fourth quarter of fiscal 2002, we changed the expected term of the agreement to four years to reflect the revised estimated timing of our research and development commitment for Tarceva(TM) under the alliance. The revision was a result of the review of the current research data available, current developments in the HER1/EGFR targeted therapy market and the involved parties' revised projections for the clinical development plan. In accordance with Accounting Principles Board Opinion No. 20, "Accounting Changes," the remaining deferred revenue will be recognized prospectively over the revised term. As a result, we recorded revenues of \$1.3 million in the first quarter of fiscal 2003 compared to \$2.1 million in the first quarter of fiscal 2002. This decrease was also due to a decrease in revenues from certain administrative services provided to British Biotech plc during the transition period following the acquisition of certain assets from British Biotech.

EXPENSES

Operating expenses of \$35.8 million decreased \$117.8 million or 77% for the three months ended December 31, 2002 compared to the three months ended December 31, 2001. Excluding the in-process R&D charge of \$130.2 million recorded in the three months ended December 31, 2001, operating expenses increased \$12.4 million or 53% for the three months ended December 31, 2002 compared to the three months ended December 31, 2001. Operating expenses primarily included (i) research and development expenses, which include expenses related to the development of our lead clinical candidate, Tarceva(TM), and proprietary and collaborative-based research; (ii) the \$130.2 million charge related to the acquired in-process R&D related to the oncology assets acquired from Gilead in December 2001; (iii) selling, general and administrative expenses; and (iv) amortization of intangibles. We intend to hold our core operating costs, including expenses related to Tarceva(TM) development, to approximately \$140 - \$145 million for fiscal 2003.

Research and development expenses increased \$11.0 million or 64% for

the three months ended December 31, 2002 compared to the three months ended December 31, 2001. The increase was related primarily to increased costs associated with (i) the clinical development of Tarceva(TM) under our Tripartite Agreement with Genentech and Roche and (ii) increased investments in our proprietary cancer programs, including oncology candidates acquired from Gilead in December 2001. These increases were slightly offset by a decrease in collaborative-based research expenses in comparison to the prior period. Included in research and development expenses for the three months ended December 31, 2002 is a severance charge of \$694,000. The charge related to a reduction in headcount in October 2002 as we refocus our business on oncology and away from services that we had historically provided to our former collaborative partners.

In connection with the acquisition of certain assets from Gilead in December 2001, we recorded an in-process R&D charge of \$130.2 million during the three months ended December 31, 2001, representing the estimated fair value of the acquired in-process technology that had not yet reached technological feasibility and had no alternative future use (see note 3 to the accompanying consolidated financial statements). We obtained a third-party valuation to assist us in determining the fair value of certain assets. The value was determined by estimating the costs to develop the purchased in-process technology into commercially viable products, estimating the resulting net cash flow from such projects and discounting the net cash flows back to their present value. These cash flows were probability-adjusted to take into account the uncertainty surrounding the successful development and commercialization of the acquired in-process technology. The resulting net cash flows were based on estimated revenue, cost of sales, R&D costs, selling, general and administrative costs, and the net cash flow reflects the assumptions that would be used by market participants. We believe that the assumptions used in the valuation of purchased in-process technology represented a reasonable estimate of the future benefits attributable to the purchased in-process technology at the time of the acquisition. No assurance can be given that actual results will not deviate from those

15

assumptions in future periods. The acquired in-process R&D was allocated to the following three oncology candidates: OSI-211, OSI-7904L and OSI-7836.

As of December 31, 2002, the technological feasibility of the three candidates (acquired in-process technology) had not yet been reached. For each project, we need to successfully complete a series of clinical trials and to receive FDA or other regulatory approvals prior to commercialization. There can be no assurances that any of these candidates will ever reach feasibility or develop into products that can be marketed profitably, nor can there be assurance we will be able to develop and commercialize these products prior to the development of comparable products by our competitors. If it is determined that it is not cost beneficial to pursue the further development of any of these candidates, we may discontinue such further development of certain or all of these candidates.

Selling, general and administrative expenses increased \$1.6 million or 28% for the three months ended December 31, 2002 compared to the three months ended December 31, 2001. The increase was due to increased commercialization and marketing costs relating to Tarceva(TM) which are shared with Genentech in accordance with the terms of our collaboration with Genentech. This increase was offset slightly by a decrease in relocation expenses relating to the consolidation of the Birmingham, England facility with our Oxford, England facility. Included in selling, general and administrative expenses for the three months ended December 31, 2002 is a severance charge of \$249,000 relating to a reduction in headcount in October 2002. We anticipate that general and administrative expenses will remain relatively steady during fiscal 2003 with an increase in commercialization and marketing costs as we expand our commercial operations in preparation for the launch of Tarceva(TM) and other development programs.

Amortization of intangibles decreased \$255,000 or 83% for the three months ended December 31, 2002 compared to the three months ended December 31, 2001. The decrease was attributable to the full adoption of SFAS No. 142 on October 1, 2002, whereby we ceased amortizing the assembled workforce acquired from British Biotech and reclassified the balance of \$2.1 million to goodwill.

OTHER INCOME AND EXPENSE

Net investment income decreased \$1.9 million or 42% for the three months ended December 31, 2002 compared to the three months ended December 31, 2001. The decrease was primarily attributable to a decrease in the average rate of return on our investments and to less funds available for investment during the respective periods. Interest expense increased \$1.6 million for the three months ended December 31, 2002 compared to the three months ended December 31, 2001, primarily due to the interest expense incurred on the convertible senior subordinated notes issued in February 2002, a portion of which were retired in August and September 2002. The convertible senior subordinated notes bear interest at 4% per annum, payable semi-annually, and mature on February 1, 2009. For the three months ended December 31, 2002 and 2001, other income-net was \$143,000 and \$773,000, respectively.

16

Included in the three months ended December 31, 2002 was realized gains from the sale of investments of \$345,000 offset by the amortization of debt issuance costs of \$203,000. Included in the three months ended December 31, 2001 was the \$1.0 million contingent payment received from The Bayer Corporation in December 2001, in connection with the sale of the diagnostic business in November 1999, offset by realized losses from the sale of investments of \$269,000.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2002, working capital, representing primarily cash, cash equivalents, and restricted and unrestricted short-term investments, aggregated \$415.2 million compared to \$444.6 million at September 30, 2002. This decrease of \$29.3 million resulted primarily from our net operating cash burn for the period.

On February 1, 2002, we issued \$200.0 million aggregate principal amount of convertible senior subordinated notes in a private placement for net proceeds to us of approximately \$193.0 million. The notes bear interest at 4% per annum, payable semi-annually, and mature on February 1, 2009. We pledged \$22.9 million of U.S. government securities which will be sufficient to provide for the payment in full of the first six scheduled interest payments on the notes when due. In August and September 2002, we retired a total of \$40.0 million in principal amount of the notes for an aggregate purchase price of \$26.2 million, including accrued interest. Should conditions warrant, we may from time-to-time continue to enter the market to repurchase additional notes.

We expect to incur continued losses over the next several years as we continue our investment in Tarceva(TM) and other product candidates in our pipeline. The major expenses associated with the broad-based Phase III development program for Tarceva(TM) are expected to occur in fiscal 2003 and, as a result, we expect our operating expenses and cash burn to increase in fiscal 2003. Beyond fiscal 2003, as the Tarceva(TM) development expenses begin to wind down, we expect a lower operating expense and cash burn base which we will maintain until a successful Tarceva(TM) market launch. We have established a goal of achieving profitability and positive cash flow within 18 to 24 months of a successful market launch of Tarceva(TM). Although we believe that we have sufficient cash for operations for the next few years, if the market launch of Tarceva(TM) is delayed or if Tarceva(TM) does not receive FDA approval or if the approval process is delayed or takes longer than expected, such events could have a negative impact on our liquidity position, assuming our current cash burn. In addition, as we pursue our goal of securing strategic in-licensing and acquisition opportunities that would bring products and clinical development candidates to our cancer pipeline, this will require the use of our available cash and/or equity securities.

To achieve profitability, we, alone or with others, must successfully develop and commercialize our technologies and products, conduct pre-clinical studies and clinical trials, secure required regulatory approvals and obtain adequate assistance to successfully manufacture, introduce and market such technologies and products. The ability and time

17

required to reach profitability is uncertain. We believe that our existing cash

resources provide a strong financial base from which to fund our operations and capital requirements for at least the next several years.

COMMITMENTS AND CONTINGENCIES

Our major outstanding contractual obligations relate to our convertible senior subordinated notes and our facility leases. The following table summarizes our significant contractual obligations at December 31, 2002 and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

<TABLE>
<CAPTION>

	2003	2004	2005	2006	2007	2008 & THEREAFTER	TOTAL
	----	----	----	----	----	-----	-----
<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
Contractual Obligations:							
Senior convertible debt(a).	\$ 6,400	\$6,400	\$6,400	\$6,400	\$6,400	\$169,600	\$201,600
Operating leases.....	5,523	7,168	7,098	5,632	4,296	56,646	86,363
Construction commitments...	111	--	--	--	--	--	111
Loans payable(b)	435	--	--	--	--	--	435
	-----	-----	-----	-----	-----	-----	-----
Total contractual obligations.....	\$12,469	\$13,568	\$13,498	\$12,032	\$10,696	\$226,246	\$288,509
	=====	=====	=====	=====	=====	=====	=====

</TABLE>

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- (a) Includes interest payments at a rate of 4% per annum
(b) Includes interest payments

Other significant commitments and contingencies include the following:

- o We are committed to share equally with Genentech and Roche certain global development costs of Tarceva(TM). We are also committed to share certain commercialization cost relating to Tarceva(TM) with Genentech.
 - o In connection with the acquisition of certain of Gilead's oncology assets in December 2001, we are obligated to pay up to an additional \$30.0 million in either cash or a combination of cash and common stock upon the achievement of certain milestones related to the development of OSI-211, the most advanced of Gilead's oncology product candidates acquired by us.
 - o Under agreements with external clinical research organizations, or CROs, over the next 12 to 18 months we will continue to incur expenses relating to the progress of Tarceva(TM) clinical trials. These disbursements can be based upon the achievement of certain milestones, patient enrollment, services rendered or as expenses are incurred by the CROs.
- 18
- o In connection with our strategic decision to close down our Birmingham, England facility, we expect to pay approximately \$111,000 in non-cancelable lease exit costs.
 - o We have a retirement plan which provides postretirement medical and life insurance benefits to eligible employees, board members and qualified dependents. Eligibility is determined based on age and years of service. We have accrued postretirement benefit costs of approximately \$2.6 million at December 31, 2002.
 - o Under certain collaboration agreements with pharmaceutical companies and educational institutions, we are required to pay royalties and/or milestones upon the successful development and commercialization of products.
 - o Under certain license agreements, we are required to pay license fees for the use of technologies and products in our research and

development activities.

- o We entered into a letter of credit with a commercial bank in relation to one of our facilities. The irrevocable letter of credit expires annually with a final expiration date of September 27, 2007. The amount under this letter of credit is \$2.2 million of which the full amount was available on December 31, 2002.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 2002, the FASB issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities", effective for exit or disposal activities that are initiated after December 31, 2002. Under SFAS No. 146, a liability for a cost associated with an exit or disposal activity must only be recognized when the liability is incurred. Under the previous guidance of EITF 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity including Certain Costs Incurred in a Restructuring", we recognized a liability for an exit or disposal activity cost at the date of our commitment. If we were to commit to further exit or disposal activities subsequent to the effective date, we would be subject to the new rules regarding expense recognition.

In December 2002, the FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure." SFAS No. 148 provides alternative methods of transition for an entity that voluntarily changes to the fair value based method of accounting for stock-based employee compensation. It also amends the disclosure provisions of SFAS No. 123 to require prominent disclosure about the effects on reported net income of an entity's accounting policy decisions with respect to stock-based employee compensation and is effective for financial statements for fiscal years ending after December 15, 2002. We are currently assessing the impact of adoption of SFAS No. 148.

19

In November 2002, the FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others." Interpretation No. 45 requires a guarantor to include disclosure of certain obligations, and if applicable, at the inception of the guarantee, recognize a liability for the fair value of other certain obligations undertaken in issuing a guarantee. The recognition requirement is effective for guarantees issued or modified after December 31, 2002 and is not expected to have a material impact on us.

In January 2003, the FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities." FIN 46 clarifies the application of Accounting Research Bulletin No. 51 to require consolidation of an entity if it is controlled through interests other than voting interests. FIN 46 applies immediately to any variable interest entities created after January 31, 2003 and to variable interest entities in which an interest is obtained after that date. It is applicable for us in the fourth quarter of fiscal year 2003, which ends September 30, 2003, for interests acquired in variable interest entities prior to February 1, 2003. We are currently assessing the impact of adoption of FIN 46.

FORWARD LOOKING STATEMENTS

A number of the matters and subject areas discussed in this Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations," and elsewhere in this report that are not historical or current facts deal with potential future circumstances and developments. The discussion of these matters and subject areas is qualified by the inherent risks and uncertainties surrounding future expectations generally, and these discussions may materially differ from our actual future experience involving any one or more of these matters and subject areas. These forward looking statements are also subject generally to the other risks and uncertainties that are described in our annual report on Form 10-K, as amended, for the fiscal year ended September 30, 2002.

20

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our cash flow and earnings are subject to fluctuations due to changes in interest rates in our investment portfolio of debt securities, to the fair value of equity instruments held and to foreign currency exchange rates. We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a component of accumulated other comprehensive income (loss) included in stockholders' equity. With respect to the convertible senior subordinated notes, we pledged \$22.9 million of U.S. government securities (restricted investment securities) with maturities at various dates through November 2004. Upon maturity, the proceeds of the restricted investment securities will be sufficient to pay the first six scheduled interest payments on the convertible senior subordinated notes when due. We consider our restricted investment securities to be "held-to-maturity," as defined by SFAS No. 115, "Accounting for Certain Investments in Debt and Equity Securities." These securities are reported at their amortized cost, which includes the direct costs to acquire the securities, plus the amortization of any discount or premium, and accrued interest earned on the securities. Our limited investments in certain biotechnology companies are carried on the equity method or cost method of accounting using the guidance of applicable accounting literature. Other-than-temporary losses are recorded against earnings in the same period the loss was deemed to have occurred. It is uncertain whether other-than-temporary losses will be material to our results of operations in the future. We do not currently hedge these exposures. We at times minimize risk by hedging the foreign currency exchange rates exposure through forward contracts as more fully described in note 12(d) to the consolidated financial statements contained in our annual report on Form 10-K, as amended, for the fiscal year ended September 30, 2002. We did not have any forward foreign exchange contracts as of or during the three months ended December 31, 2002.

At December 31, 2002, we maintained a portion of our cash and cash equivalents in financial instruments with original maturities of three months or less. We also maintained an investment portfolio containing financial instruments of which approximately 3% have original maturities of less than 12 months. These financial instruments, principally comprised of government and government agency obligations and corporate obligations, are subject to interest rate risk and will decline in value if interest rates increase. A hypothetical 10% change in interest rates during the three months ended December 31, 2002 would have resulted in a \$267,000 change in our net loss. We have not used or held derivative financial instruments in our investment portfolio.

Our long-term debt totaled \$160.0 million at December 31, 2002 and was comprised of the convertible senior subordinated notes. The convertible senior subordinated notes bear interest at a fixed rate of 4%.

Underlying market risk exists related to an increase in our stock price or an increase in interest rates which may make the conversion of the convertible senior subordinated notes to

common stock beneficial to the convertible senior subordinated notes holders. Conversion of the convertible senior subordinated notes would have a dilutive effect on any future earnings and book value per common share.

ITEM 4. CONTROLS AND PROCEDURES

CEO and CFO Certifications. Appearing immediately following the Signatures section of this Quarterly Report there are two certifications, or the Section 302 Certifications, one by each of our Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO. This section of the Quarterly Report which you are currently reading contains information concerning the evaluation of our disclosure controls and procedures and internal controls that is referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Evaluation of our Disclosure Controls and Procedures. The Securities and Exchange Commission requires that within 90 days prior to the filing of this Quarterly Report on Form 10-Q, the CEO and the CFO evaluate the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13(a)-14(c) and Rule 15(d)-19(c) under the Securities Exchange Act of

1934), and report on the effectiveness of the design and operation of our disclosure controls and procedures. Within 90 days prior to the filing of this Quarterly Report on Form 10-Q, under the supervision and with the participation of our management, including our CEO and CFO, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures.

Limitations on the Effectiveness of Controls. Our management, including the CEO and CFO, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing we intend to continue to examine and refine our disclosure controls and procedures and to monitor ongoing developments in this area.

22

CEO/CFO Conclusions about the Effectiveness of the Disclosure Controls and Procedures. Based upon their evaluation of the disclosure controls and procedures, our CEO and CFO have concluded that, subject to the limitations noted above, our disclosure controls and procedures are effective to provide reasonable assurance that material information relating to the Company and its consolidated subsidiaries is made known to management, including the CEO and CFO, on a timely basis and particularly during the period in which this Quarterly Report on Form 10-Q was being prepared.

Changes in Internal Controls. There were no significant changes to our internal controls or in other factors that could significantly affect our internal controls, subsequent to the date of our last evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

23

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Not applicable.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Not applicable.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

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

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) EXHIBITS

- 3.1 Certificate of Incorporation, as amended, filed by OSI Pharmaceuticals, Inc. as an exhibit to the Form 10-K for the fiscal year ended September 30, 2001 (file no. 000-15190), and incorporated herein by reference.
- 3.2 Amended and Restated Bylaws, filed by OSI Pharmaceuticals, Inc. as an exhibit to the Form 10-K for the fiscal year ended September 30, 2001 (file no. 000-15190), and incorporated herein by reference.
- 10.1* Amended and Restated Stock Purchase Plan for Non-Employee Directors.
- 10.2* First Amendment to the 2001 Incentive and Non-Qualified Stock Option Plan.
- 99.1* Certification of Chief Executive Officer pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

24

- 99.2* Certification of Chief Financial Officer pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

(b) REPORTS ON FORM 8-K

We filed a current report on October 1, 2002 with the Securities and Exchange Commission via EDGAR, pertaining to three press releases. One press release announced an update and commentary on the progress of our clinical trial candidate, Tarceva(TM) (erlotinib HCl), following a release announcing unfavorable results of a competitor's drug candidate which belongs to the same class of targeted therapies as Tarceva(TM). Another press release announced the Food and Drug Administration's designation of Tarceva(TM) as a Fast Track Product for second-line or third line treatment of patients with certain types of non-small cell lung cancer and also announced adjustments in two of the registration studies in the OSI-Genetech-Roche alliance for Tarceva(TM). The third press release announced that we had repurchased \$40 million aggregate principal amount of the convertible senior subordinated notes originally issued in February 2002 in the open market for approximately \$26 million. The earliest event covered by the report occurred on August 19, 2002.

25

SIGNATURES

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

OSI PHARMACEUTICALS, INC.

(Registrant)

Date: February 7, 2003

/s/ Colin Goddard, Ph.D.

Colin Goddard, Ph.D.
Chief Executive Officer

Date: February 7, 2003

/s/ Robert L. Van Nostrand

Robert L. Van Nostrand
Vice President and Chief Financial Officer
(Principal Financial Officer)

26

CERTIFICATION

I, Colin Goddard, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OSI Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

27

6. The registrant's other certifying officer and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ COLIN GODDARD, Ph.D

Colin Goddard, Ph.D
Chief Executive Officer

28

CERTIFICATION

I, Robert L. Van Nostrand, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OSI Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and have:

(a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

(b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

(c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

29

6. The registrant's other certifying officer and I have indicated in this quarterly report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Robert L. Van Nostrand
Vice President and Chief Financial Officer

30

INDEX TO EXHIBITS

Exhibit

- 3.1 Certificate of Incorporation, as amended, filed by OSI Pharmaceuticals, Inc. as an exhibit to the Form 10-K for the fiscal year ended September 30, 2001 (file no. 000-15190), and incorporated herein by reference.
- 3.2 Amended and Restated Bylaws, filed by OSI Pharmaceuticals, Inc. as an exhibit to the Form 10-K for the fiscal year ended September 30, 2001 (file no. 000-15190), and incorporated herein by reference.
- 10.1* Amended and Restated Stock Purchase Plan for Non-Employee Directors.
- 10.2* First Amendment to the 2001 Incentive and Non-Qualified Stock Option Plan.
- 99.1* Certification of Chief Executive Officer pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 99.2* Certification of Chief Financial Officer pursuant to 18 U.S.C. ss.1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

* Filed herewith.

31

OSI PHARMACEUTICALS, INC.

AMENDED AND RESTATED
STOCK PURCHASE PLAN FOR
NON-EMPLOYEE DIRECTORS

OSI Pharmaceuticals, Inc. (formerly known as Oncogene Science, Inc.), a Delaware corporation (the "Company"), has adopted a Stock Purchase Plan (the "Director Plan") for non-employee Directors of the Company, as amended and restated, as follows:

I. PURPOSE - The purpose of the Director Plan is to provide Non-Employee Directors an opportunity to participate in the future growth and profitability of the Company through the payment of all or a portion of the Directors' retainer fees and meeting attendance fees in Common Stock of the Company.

II. SHARES SUBJECT TO THE DIRECTOR PLAN - The shares of Common Stock to be issued pursuant to the Director Plan shall be either shares of authorized but unissued Common Stock or shares of Common Stock reacquired by the Company. Subject to the provisions of Section VI hereof, the number of shares of Common Stock which may be granted to Directors hereunder shall not exceed 100,000 shares.

III. DEFINITIONS

"Attendance Fees" means the meeting attendance fees at the rate payable to Directors for attendance at meetings of the Board of Directors and committees of the Board, as such fees shall be in effect on the date of an Election under this Director Plan.

"Attendance Share" means each share of Common Stock granted under this Director Plan upon the Election of a Non-Employee Director to receive shares of Common Stock in lieu of a portion of such Director's Attendance Fees."

"Common Stock" means shares of the Company's Common Stock, \$.01 par value.

"Company" means OSI Pharmaceuticals, Inc., a Delaware corporation.

"Date of Grant" means (1) with respect to each Mandatory Retainer Share and each Optional Retainer Share, the first day of the one-year term of Board membership to which the Mandatory or Optional Share relates; and (2) with respect to each Attendance Share, the date that an Attendance Fee shall be earned.

"Effective Date" means the date this Plan is adopted by the stockholders of the Company.

"Election" means a valid election to acquire shares of Common Stock made pursuant to the terms and conditions of this Director Plan.

"Election Percentage" means the percentage of a Director's Attendance Fees and Optional Retainer Fees foregone in lieu of the Plan Shares elected to be acquired hereunder.

"Election Period" means the period commencing on the first day of the next calendar month following the expiration of six months after an Election by a Director and terminating on the first day of the next calendar month following the expiration of six months' written notice by a Director of his withdrawal from participation in this Director Plan.

"Fair Market Value" means the closing price of the Common Stock on the National Association of Securities Dealers National Market ("NMS"), or, if there shall not be any reported transaction in the Common Stock on such date, the mean between the highest last reported bid price and the lowest last reported asked price, as reported by NMS.

"Mandatory Retainer Share" means each share of Common Stock granted under this Director Plan in payment of 50% of a Director's Retainer Fees.

"Non-Employee Director" means any Director of the Company who is not an employee of the Company or any of its subsidiaries.

"Optional Retainer Fees" means 50% of the Retainer Fees.

"Optional Retainer Share" means each share of Common Stock granted under this Director Plan upon the Election of a Non-Employee Director to receive shares of Common Stock in lieu of all or part of such Director's Optional Retainer Fees.

"Plan Shares" means all Optional and Mandatory Retainer Shares and Attendance Shares.

"Retainer Fees" means the monthly retainer fees at the rate payable to Directors, as such fees shall be in effect on the date of an Election under this Directors' Plan.

"Retainer Share" means each share of Common Stock granted under this Director Plan upon the Election of a Non-Employee Director to receive shares of Common Stock in lieu of all or part of such Director's Retainer Fees."

IV. ADMINISTRATION - This Director Plan shall be administered by such officers of the Company as the Board of Directors shall from time to time appoint; provided that the interpretation and construction of any provision of this Director Plan or any Election shall remain with the Board of Directors, and any such determination by the Board of Directors shall be final and conclusive. The amount, price, and timing of the grants of Plan Shares hereunder shall be

automatic, as described herein.

V. GRANT OF SHARES - Subject to the terms and conditions of this Director Plan, Non-Employee Directors are hereby granted as of each Date of Grant: (1) those Plan Shares as to

2

which they make a valid Election pursuant to the terms of this Director Plan and (2) Mandatory Retainer Shares.

VI. ADJUSTMENTS UPON CHANGES IN CAPITALIZATION - The aggregate number of shares of Common Stock available for grant hereunder shall be appropriately adjusted by the Board of Directors in the event of any recapitalization or similar transaction or event.

VII. EFFECTIVE AND EXPIRATION DATES OF THE DIRECTOR PLAN - This Director Plan shall be effective upon adoption by the Board of Directors, subject to the approval of the stockholders of the Company. This Director Plan shall expire ten years from the date of adoption by the Board of Directors.

VIII. ELECTIONS - All Elections shall be made upon the following terms and conditions:

Each Non-Employee Director shall have the right (1) to elect to receive Attendance Shares in lieu of a portion of the Director's Attendance Fees and (2) to elect to receive Optional Retainer Shares in lieu of a portion of the Director's Optional Retainer Fees.

All Elections in respect of Attendance Fees shall be in writing, shall be made by delivery of an Election to the Secretary of the Company at least six months prior to the month in which the Election is to be effective and shall indicate the Election Percentage for Attendance Shares. A Director may change an Election Percentage in respect of Attendance Fees upon six months' written notice to the Secretary of the Company.

All Elections in respect of Optional Retainer Fees shall be made in writing by delivery of an Election to the Secretary of the Company no later than the first day of the Board term to which the Election is to be effective. Such Election shall indicate the Election Percentage for Optional Retainer Shares and shall remain in effect for all subsequent Board terms unless the Non-Employee Director changes his Election by providing written notice to the Secretary of the Company. A change in such Election shall not be effective until the first day of the Board term that is coincident with or next following the date such change in Election is delivered to the Secretary of the Company.

No Election shall be effective with respect to any Plan Share unless the Non-Employee Director making the Election is still a Non-Employee Director on the Date of Grant of the Plan Share. As a further condition to an effective Election, each Non-Employee Director shall agree in writing not to sell, transfer or assign any Plan Shares on or before six (6) months from the Date of Grant of the Plan Share, as determined under Rule 16b-3 of the regulations promulgated by the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

IX. TERMS AND CONDITIONS OF GRANT

The number of Attendance Shares which shall be granted to a Non-Employee Director, with respect to each Attendance Fee during the Election Period, shall equal the Attendance Fee multiplied by the Election Percentage divided by the Fair Market Value of the shares of Common Stock at the close of business on the date such Attendance Fee shall be earned.

The number of Mandatory Retainer Shares which shall be granted to a Non-Employee Director as of each Date of Grant, shall equal 50% of the annualized Retainer Fee divided by the Fair Market Value of a share of Common Stock as of the Date of Grant. The number of Optional Retainer Shares which shall be granted to a Non-Employee Director as of each Date of Grant, shall equal the Optional Retainer Fee multiplied by the applicable Election Percentage divided by the Fair Market Value of a share of Common Stock as of the Date of Grant.

Mandatory and Optional Retainer Shares granted as of each Date of Grant shall vest ratably in twelve installments as of each monthly anniversary of the Date of Grant. In the event a Non-Employee Director's service as such terminates prior to the end of any Board term, any unvested portion of his Mandatory or Optional Retainer Shares shall be forfeited.

Notwithstanding anything in this Plan to the contrary, a Non-Employee Director shall have no right to transfer his Mandatory or Optional Retainer Shares until the first annual anniversary of the Date of Grant of such Mandatory or Optional Retainer Shares.

The Company may impose such restrictions on any Plan Shares acquired under this Director Plan as may be advisable in its judgment to ensure compliance with applicable federal or state securities laws and may legend the certificates representing such Plan Shares as an appropriate notice of such restrictions.

X. DISCONTINUANCE AND AMENDMENT

The Board of Directors may, from time to time, amend, suspend or

discontinue this Director Plan, provided that any amendment that would (1) increase the aggregate number of shares of Common Stock which may be granted under the Plan, (2) materially increase the benefits accruing to Non-Employee Directors under this Director Plan, (3) materially modify the requirements as to eligibility for participation in this Director Plan, or (4) extend the expiration date of this Director Plan beyond that set forth in Section VII hereof, shall be subject to the requisite approval of the Company's stockholders. Notwithstanding the foregoing, in no event shall this Director Plan be modified more often than once every six months, other than to comport with changes in the Internal Revenue Code, the Employee Retirement Income Security Act, or the rules thereunder, or the Rules promulgated by the Securities and Exchange Commission.

The Board of Directors, without further approval of the stockholders, may terminate or suspend this Director Plan. Any such termination or suspension of the Director Plan shall not affect Plan Shares already granted.

OSI PHARMACEUTICALS, INC.

FIRST AMENDMENT TO THE
2001 INCENTIVE AND NON-QUALIFIED STOCK OPTION PLAN

Pursuant to the powers reserved to the Board of Directors of OSI Pharmaceuticals, Inc., a Delaware corporation (the "Company"), under Section 7 of Company's 2001 Incentive and Non-Qualified Stock Option Plan (the "Plan"), the Plan is hereby amended as follows, effective January 1, 2003:

FIRST AND ONLY CHANGE

Section 11(a) of the Plan is amended to read as follows:

"(a) (i) Each director, who is not also an employee of the Company or any of its affiliates, or the designee of any stockholder of the Company pursuant to a right to designate one or more directors (an "Eligible Director") who first becomes an Eligible Director on or after June 13, 2001 but prior to January 1, 2003, shall automatically be awarded a grant of 30,000 non-qualified stock options upon his or her initial election to the Board of Directors. An Eligible Director receiving an initial option grant under this Section 11(a) (i) shall not be eligible for an initial grant of option under any other stock option plan maintained by the Company. Such options shall vest and be exercisable solely in accordance with the following schedule:

(A) The options may be exercised with respect to a maximum of one-half of the option shares during the twelve-month period beginning after the date of grant.

(B) The options may be exercised with respect to all of the option shares upon the Eligible Director's reelection to the Board of Directors for a second consecutive term.

(C) The options will expire and will no longer be exercisable as of the tenth anniversary of the date of grant, subject to sooner expiration upon the occurrence of certain events as provided elsewhere in this Plan.

(a) (ii) Each Eligible Director who first becomes an Eligible Director on or after January 1, 2003, shall automatically be awarded a grant of 50,000 non-qualified stock options upon his or her initial election to the Board of Directors. An Eligible Director receiving an initial option grant under this Section 11(a) (ii)

shall not be eligible for an initial grant of option under any other stock option plan maintained by the Company. Such options shall vest and be exercisable solely in accordance with the following schedule:

(A) The options shall not be exercisable during the twelve-month period beginning after the date of grant.

(B) The options may be exercised with respect to one-third of the option shares after the expiration of twelve months from the date of grant.

(C) The remaining two-thirds of the options shall vest and become exercisable ratably on a monthly basis over the two-year period commencing one year from the date of grant and ending three years from the date of grant.

(D) The options will expire and will no longer be exercisable as of the tenth anniversary of the date of grant, subject to sooner expiration upon the occurrence of certain events as provided elsewhere in this Plan."

OSI PHARMACEUTICALS, INC.

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

In connection with the Quarterly Report of OSI Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Colin Goddard, Ph.D., Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 7, 2003

/s/ Colin Goddard, Ph.D.

Colin Goddard, Ph.D.
Chief Executive Officer

OSI PHARMACEUTICALS, INC.

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

In connection with the Quarterly Report of OSI Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended December 31, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Robert L. Van Nostrand, Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: February 7, 2003

/s/ Robert L. Van Nostrand

Robert L. Van Nostrand
Vice President and Chief Financial Officer