

FOREST LABORATORIES INC
Form 10-Q
February 13, 2004

FORM 10-Q
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 1934

For the Quarterly Period Ended December 31, 2003

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the transition period from ____ to ____

Commission File No. 1-5438

FOREST LABORATORIES, INC.

(Exact name of registrant as specified in its charter)

Delaware

11-1798614

*(State or other jurisdiction of
incorporation or organization)*

*(I.R.S. Employer
Identification Number)*

909 Third Avenue
New York, New York

10022-4731

(Address of principal executive offices)

(Zip code)

(212) 421-7850

(Registrant's telephone number, including area code)

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 No .

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

Number of shares outstanding of Registrant's Common Stock as of February 13, 2004:
367,794,520.

TABLE OF CONTENTS
(*Quick Links*)

[PART I -](#)

[FINANCIAL INFORMATION](#)

[ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS:](#)

[BALANCE SHEETS](#)
[STATEMENTS OF INCOME](#)
[STATEMENTS OF COMPREHENSIVE INCOME](#)
[STATEMENTS OF CASH FLOWS](#)
[NOTES TO FINANCIAL STATEMENTS](#)

[ITEM 2.](#)

[MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL
CONDITION AND RESULTS OF OPERATIONS](#)

[ITEM 3.](#)

[QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT
MARKET RISK](#)

[ITEM 4. CONTROLS AND PROCEDURES](#)

[PART II -](#)

[OTHER INFORMATION](#)

[ITEM 1.](#)

[LEGAL PROCEEDINGS](#)

[ITEM 6.](#)

[EXHIBITS AND REPORTS ON FORM 8-K](#)

SIGNATURESPART I - FINANCIAL INFORMATIONFOREST LABORATORIES, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(In thousands)	December 31, 2003 <u>(Unaudited)</u>	<u>March 31, 2003</u>
<u>Assets</u>		
Current assets:		
Cash (including cash equivalent investments of \$1,545,552 in December and \$1,263,156 in March)	\$1,547,057	\$1,265,508
Marketable securities	79,817	176,338
Accounts receivable, less allowance for doubtful accounts of \$19,693 in December and \$16,925 in March	284,896	192,067
Inventories, net	507,867	452,886
Deferred income taxes	143,070	156,957
Other current assets	<u>16,945</u>	<u>11,577</u>
 Total current assets	 <u>2,579,652</u>	 <u>2,255,333</u>
 Marketable securities	 <u>322,543</u>	 <u>114,639</u>
 Property, plant and equipment	 376,205	 304,818
Less: accumulated depreciation	<u>102,729</u>	<u>86,820</u>
	 <u>273,476</u>	 <u>217,998</u>
 Other assets:		
Goodwill	14,965	14,965
License agreements, product rights and other intangibles, less accumulated amortization		

Edgar Filing: FOREST LABORATORIES INC - Form 10-Q

of \$238,788 in December and \$221,099 in March	274,232	279,171
Deferred income taxes	16,916	17,627
Other	<u>16,689</u>	<u>18,374</u>
Total other assets	<u>322,802</u>	<u>330,137</u>
Total assets	\$3,498,473 =====	\$2,918,107 =====

See notes to condensed consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(In thousands, except for par values)	December 31, 2003 <u>(Unaudited)</u>	<u>March 31, 2003</u>
<u>Liabilities and Stockholders' Equity</u>		
Current liabilities:		
Accounts payable	\$ 61,780	\$ 151,719
Accrued expenses	292,832	245,240
Income taxes payable	<u>106,939</u>	<u>167,438</u>
Total current liabilities	<u>461,551</u>	<u>564,397</u>
Deferred income taxes	<u>1,669</u>	<u>1,892</u>
Stockholders' equity:		
Series A junior participating preferred stock, \$1.00 par; shares authorized 1,000; no shares issued or outstanding		
Common stock, \$.10 par; shares authorized 500,000; issued 402,711 shares in December and 399,011 shares in March	40,271	39,901
Capital in excess of par	768,254	687,905
Retained earnings	2,510,452	1,920,060
Accumulated other comprehensive income (loss)	11,648	(3,429)

Edgar Filing: FOREST LABORATORIES INC - Form 10-Q

Treasury stock, at cost (35,592 shares in December and 35,539 shares in March)	(<u>295,372</u>)	(<u>292,619</u>)
Total stockholders' equity	<u>3,035,253</u>	<u>2,351,818</u>
Total liabilities and stockholders' equity	\$3,498,473 =====	\$2,918,107 =====

See notes to condensed consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Income
(Unaudited)

(In thousands, except per share amounts)	Three Months Ended December 31,		Nine Months Ended December 31,	
	<u>2003</u>	<u>2002</u>	<u>2003</u>	<u>2002</u>
Net sales	\$700,447	\$586,804	\$1,925,352	\$1,585,592
Other income	<u>6,734</u>	<u>7,078</u>	<u>21,783</u>	<u>31,703</u>
	<u>707,181</u>	<u>593,882</u>	<u>1,947,135</u>	<u>1,617,295</u>
Costs and expenses:				
Cost of sales	160,866	134,363	439,369	364,869
Selling, general and administrative	207,869	177,163	590,405	516,983
Research and development	<u>50,581</u>	<u>51,886</u>	<u>165,748</u>	<u>153,471</u>
	<u>419,316</u>	<u>363,412</u>	<u>1,195,522</u>	<u>1,035,323</u>
Income before income tax expense	287,865	230,470	751,613	581,972
Income tax expense	<u>61,747</u>	<u>55,889</u>	<u>161,221</u>	<u>140,721</u>

Edgar Filing: FOREST LABORATORIES INC - Form 10-Q

Net income	\$226,118	\$174,581	\$ 590,392	\$ 441,251
	=====	=====	=====	=====
Net income per common and common equivalent share:				
Basic	\$0.62	\$0.48	\$1.62	\$1.23
	=====	=====	=====	=====
Diluted	\$0.60	\$0.47	\$1.57	\$1.18
	=====	=====	=====	=====
Weighted average number of common and common equivalent shares outstanding:				
Basic	365,791	361,877	364,808	360,124
	=====	=====	=====	=====
Diluted	376,507	375,417	375,593	372,849
	=====	=====	=====	=====

See notes to condensed consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Comprehensive Income
(Unaudited)

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	<u>2003</u>	<u>2002</u>	<u>2003</u>	<u>2002</u>
Net income	\$226,118	\$174,581	\$590,392	\$441,251
Other comprehensive income	<u>8,567</u>	<u>5,375</u>	<u>15,077</u>	<u>16,897</u>
Comprehensive income	\$234,685	\$179,956	\$605,469	\$458,148
	=====	=====	=====	=====

See notes to condensed consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(Unaudited)

Edgar Filing: FOREST LABORATORIES INC - Form 10-Q

(In thousands)	Nine Months Ended	
	<u>December 31,</u>	
	<u>2003</u>	<u>2002</u>
Cash flows from operating activities:		
Net income	\$ 590,392	\$ 441,251
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	15,697	15,225
Amortization, impairments and write-offs	30,234	24,644
Deferred income tax expense (benefit)	6,655	(37,044)
Foreign currency translation loss (gain)	1,383	(360)
Tax benefit realized from the exercise of stock options by employees	49,556	53,095
Net change in operating assets and liabilities:		
Decrease (increase) in:		
Accounts receivable, net	(92,829)	(38,346)
Inventories, net	(54,981)	(67,575)
Refundable income taxes		12,733
Other current assets	(5,368)	3,142
Increase (decrease) in:		
Accounts payable	(89,939)	22,805
Accrued expenses	47,592	78,415
Income taxes payable	(60,499)	28,519
Decrease in other assets	<u>1,685</u>	<u>256</u>
Net cash provided by operating activities	<u>439,578</u>	<u>536,760</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(70,459)	(60,784)
Purchase of marketable securities	(531,067)	(554,228)
Redemption of marketable securities	419,684	862,831
Purchase of license agreements, product rights and other intangibles	<u>(25,000)</u>	<u>(43,960)</u>
Net cash provided by (used in) investing activities	<u>(206,842)</u>	<u>203,859</u>

Cash flows from financing activities:

Net proceeds from common stock options exercised by employees under stock option plans	<u>36,130</u>	<u>29,895</u>
Effect of exchange rate changes on cash	<u>12,683</u>	<u>16,558</u>
Increase in cash and cash equivalents	281,549	787,072
Cash and cash equivalents, beginning of period	<u>1,265,508</u>	<u>459,861</u>
Cash and cash equivalents, end of period	\$1,547,057 =====	\$1,246,933 =====

Supplemental disclosures of cash flow information:

Cash paid during the period for:

Income taxes	\$165,345	\$83,725
--------------	-----------	----------

See notes to condensed consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation:

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of Management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the nine-month period ended December 31, 2003 are not necessarily indicative of the results that may be expected for the year ending March 31, 2004. For further information refer to the consolidated financial statements and footnotes thereto incorporated by reference in the Company's Annual Report on Form 10-K for the year ended March 31, 2003.

2. Inventories:

Inventories, net of reserves for obsolescence, consist of the following:

(In thousands)	December 31, 2003 <u>(Unaudited)</u>	<u>March 31, 2003</u>
Raw materials	\$237,770	\$101,607
Work in process	32,491	38,190
Finished goods	<u>237,606</u>	<u>313,089</u>
	\$507,867	\$452,886
	=====	=====

3. Net Income Per Share:

A reconciliation of shares used in calculating basic and diluted net income per share follows:

(In thousands)	<u>Three Months Ended</u> <u>December 31,</u>		<u>Nine Months Ended</u> <u>December 31,</u>	
	<u>2003</u>	—	<u>2003</u>	<u>2002</u>
		<u>2002</u>		
Basic	365,791	361,877	364,808	360,124
Effect of assumed conversion of employee stock options and warrants	<u>10,716</u>	<u>13,540</u>	<u>10,785</u>	<u>12,725</u>
Diluted	376,507	375,417	375,593	372,849
	=====	=====	=====	=====

Options to purchase approximately 1,443,000 shares of common stock at an exercise price of \$59.05 per share and options to purchase approximately 1,657,000 shares of common stock at exercise prices ranging from \$53.23 to \$59.05 per share that were outstanding during a portion of the three and nine-month periods ended December 31, 2003, respectively, were not included in the computation of diluted net income per share because they were anti-dilutive. There were no outstanding options or warrants excluded from the computation of diluted earnings per share for the three-month period ended December 31, 2002, as none were anti-dilutive. Options to purchase approximately 2,896,000 shares of common stock at exercise prices ranging from \$41.49 to \$48.34 per share that were outstanding during a portion of the nine-month period ended December 31, 2002 were not included in the computation of diluted earnings per share because they were anti-dilutive. These options expire through 2013.

4. Stock-Based Compensation:

The Company accounts for its stock option awards to employees under the intrinsic value based method of accounting prescribed by Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees." Under the intrinsic value based method, compensation cost is the excess, if any, of the quoted market price of the stock at grant date or other measurement date over the amount an employee must pay to acquire the stock. The Company makes pro forma disclosures of net income and earnings per share as if the fair value based method of accounting had been applied as required by Statement of Financial Accounting Standards No. 123 ("SFAS 123"), "Accounting for Stock-Based Compensation." The Company has never granted options below market price on the date of grant.

Edgar Filing: FOREST LABORATORIES INC - Form 10-Q

SFAS 123 requires the Company to provide pro forma information regarding net income and earnings per share as if compensation cost for the Company's stock option plans had been determined in accordance with the fair value of each stock option at the grant date by using the Black-Scholes option-pricing model with the following weighted average assumptions used for grants for the three and nine-month periods ended December 31, 2003 and December 31, 2002: dividend yield of zero; expected volatility of 22.46% and 31.29%, respectively; risk-free interest rate of 4.3%; and expected lives of 5 to 10 years.

Under the accounting provisions of SFAS 123, the Company's net income and earnings per share would have been reduced to the pro forma amounts indicated below:

(In thousands, except per share data)	<u>Three Months Ended</u> <u>December 31,</u>		<u>Nine Months Ended</u> <u>December 31,</u>	
	<u>2003</u>	<u>2002</u>	<u>2003</u>	<u>2002</u>
Net income:				
As reported	\$226,118	\$174,581	\$590,392	\$441,251
Deduct: Total stock-based employee compensation expense determined under fair value method, net of taxes	(9,439)	(6,199)	(26,624)	(19,610)
Pro forma	\$216,679	\$168,382	\$563,768	\$421,641
	=====	=====	=====	=====
Net income per common share:				
Basic:				
As reported	\$0.62	\$0.48	\$1.62	\$1.23
Pro forma	\$0.59	\$0.47	\$1.55	\$1.17
Diluted:				
As reported	\$0.60	\$0.47	\$1.57	\$1.18
Pro forma	\$0.58	\$0.45	\$1.50	\$1.13

FOREST LABORATORIES, INC. AND SUBSIDIARIES

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

The Company posted record revenues and earnings for the third quarter which will be discussed further in Results of Operations. Key events during the quarter were two significant product approvals by the Food and Drug Administration (FDA): Namenda™ for the treatment of moderate to severe Alzheimer's disease and Lexapro® for the treatment of generalized anxiety disorder (GAD), which were approved in October and December, respectively. Both products will be an important component of the continued growth of the Company over the next several years. Namenda is scheduled for launch in early March and Lexapro for GAD was launched in January 2004. Also encouraging was a positive study outcome for the mild to moderate monotherapy study for Namenda which will support a supplemental New Drug Application (sNDA) for that indication sometime next fiscal year.

Critical Accounting Policies

The following accounting policies are important in understanding the Company's financial condition and results of operations and should be considered an integral part of the financial review. Refer to Notes 1 through 4 to the

consolidated financial statements for additional policies.

Estimates and Assumptions

The preparation of financial statements in conformity with generally accepted accounting principles requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and of revenues and expenses during the reporting period. Estimates are made when accounting for sales allowances, returns, rebates and other pricing adjustments, depreciation, amortization and certain contingencies. The Company is subject to risks and uncertainties, which may include but are not be limited to competition, federal or local legislation and regulations, litigation and overall changes in the healthcare environment that may cause actual results to vary from estimates. The Company reviews all significant estimates affecting the financial statements on a recurring basis and records the effect of any adjustments when necessary. Certain of these risks, uncertainties and assumptions are discussed further under the section entitled "Forward Looking Statements".

Goodwill and Other Intangible Assets

The Company has made acquisitions in the past that include goodwill, license agreements, product rights and other intangibles. Through fiscal 2001, these assets were amortized over their estimated useful lives, and were tested periodically to determine if they were recoverable from operating earnings on an undiscounted basis over their useful lives.

Effective with fiscal 2002, goodwill was no longer amortized but is subject to an annual impairment test based on its estimated fair value. License agreements, product rights and other intangibles will continue to be amortized over their useful lives and tested periodically to determine if they are recoverable from operating earnings on an undiscounted basis over their useful lives.

Revenue Recognition

Revenues are recorded in the period the merchandise is shipped. Provisions for estimated sales allowances, returns, rebates and other pricing adjustments are accrued at the time revenues are recognized as a direct reduction of such revenue. The accruals are estimated based on available information regarding the portion of sales on which rebates and discounts can be earned, adjusted as appropriate for specific known events, and the prevailing contractual discount rates. Provisions are reflected either as a direct reduction to accounts receivable or, to the extent that they are due to entities other than customers, as accrued expense. Adjustments to estimates, which have not been material, are recorded when customer credits are issued or payments are made to third parties.

Financial Condition and Liquidity

Net current assets increased by \$427,165,000 from March 31, 2003. Cash and cash equivalents increased by \$281,549,000 and marketable securities increased in total by \$111,383,000 due to the continued growth of the Company's ongoing operating activities. The Company has been shifting the composition of marketable securities in favor of longer term securities to receive more favorable rates of return. The increase in accounts receivable was the result of some inventory building by wholesalers and distributors ahead of the December holiday season. The buying was across most of our branded products and occurred within our 30-day payment terms at the end of the quarter. Contributing to the increase in accounts receivable and a corresponding increase to accrued expense, was a shift of certain managed care contracts to rebate programs during the quarter. Provisions for rebates are reflected in accrued expense rather than as a reduction of accounts receivable. The decrease in accounts payable resulted principally from the timing of deliveries of raw material for Celexa and Lexapro near the end of the March 31, 2003 period. As a result, payment for a larger portion of the deliveries through March 31, 2003 was not yet due under normal payment terms which have remained unchanged.

The increase in inventories during the period was due to an increase in raw materials which was partially offset by a decrease in finished goods. Raw materials increased in volume to support increasing sales and average cost increased due to a change in the mix of materials held in inventory for sale and for sampling. Under our licensing arrangements raw materials acquired for sampling of Celexa® (citalopram) and Lexapro (escitalopram oxalate) are purchased at a discount and raw materials held for samples made up a smaller proportion of inventories as compared to March 2003, at which time Lexapro was in its launch phase. The change in the mix of inventory has no impact on gross margin as sample expense is a component of selling, general and administrative expenses. Finished goods, as a component of total inventory, decreased which was due in part to the accelerated December stock-in of Namenda. In addition, finished goods inventories at March 31, 2003 were relatively high due to the early stage of the Lexapro launch where we were maintaining safety stock levels for both Lexapro and Celexa at a high level until the rate of conversion was established. During the course of this year inventories of both have been adjusted to appropriate levels.

Property, plant and equipment increased as the result of the continuing expansion of the Company's facilities in order to meet current and future product and research and development demands. On Long Island, the Company is nearing completion of a 100,000 square foot research and development laboratory and has begun the expansion of its packaging and distribution facility, which will add approximately 185,000 square feet to that location. During the period an additional 180,000 square foot facility was purchased on Long Island and will be converted for future research and development activities. Further property expansions and acquisitions are planned in the future to meet the needs from increased sales and related production, warehousing and distribution and for products under development.

The Company is a party to several license agreements for products currently under development that may obligate Forest, in future periods, to pay additional amounts subject to the achievement of certain product development milestones, as defined. During the quarter a \$20,000,000 milestone payment was made to Merz Pharma GmbH upon FDA approval of Namenda (memantine), which was recorded in license agreements, product rights and other intangibles. During the second quarter the Company announced that it had discontinued development of dexloxiplumide for irritable bowel syndrome (IBS), causing a write-off of the license agreement of \$12,545,000 to research and development expense. Subsequent to the end of the quarter, the Company entered into a development and marketing agreement with Cypress Bioscience, Inc. for milnacipran for the treatment of fibromyalgia.

Management believes that current cash levels, coupled with funds to be generated by ongoing operations, will continue to provide adequate liquidity to facilitate potential acquisitions of products and capital investments.

Results of Operations

Net sales for the three and nine months ended December 31, 2003 increased \$113,643,000 and \$339,760,000, respectively, from the same periods last year, primarily due to the launch of Lexapro. During the quarter Lexapro, which was launched in September 2002, surpassed Celexa as our largest product with sales of \$313,696,000 as compared to Celexa sales of \$274,196,000 and contributed \$232,709,000 to the net sales change. For the nine months, Lexapro sales amounted to \$737,119,000 accounting for \$634,383,000 of the change. As anticipated, a portion of Lexapro's market share has come from Celexa which resulted in a Celexa sales decline of \$97,011,000 and \$267,414,000, respectively for the same periods of the prior year primarily due to volume. The Company anticipates further declines in Celexa sales as Lexapro continues to gain market share. At the end of the quarter, Lexapro had achieved a 16.4% share of total prescriptions in the SSRI market, while Celexa's share declined to 9.1% from a peak share of 17.5% in August 2002. Lexapro has patent protection until 2009 and the Company has applied for an extension to 2012. On August 11, 2003 the Company received notification from a generic manufacturer that it had filed an Abbreviated New Drug Application (ANDA) with a Paragraph IV Certification with the FDA for a generic equivalent to Lexapro. The Company believes that its patents on Lexapro are valid and expects to defend its rights under those patents which would preclude the introduction of a generic product at least until after the expiration of our substance patent, including patent extension, which will be in 2012. The Company has commenced an action for patent infringement against the third party ANDA filer. Celexa had Hatch-Waxman marketing exclusivity through July 2003 and was granted a six-month extension based upon the submission of results of clinical studies in depressed

pediatric patients. Therefore, January 17, 2004 was the first date at which a generic competitor was able to file an ANDA for review by the FDA, and the Company believes that several have. During the quarter, the Company recorded stocking sales of \$11,177,000 for Namenda. Namenda, for the treatment of moderate to severe Alzheimer's disease, will be launched by Forest's salesforce on March 1, 2004, but the demand for the product is such that the Company made it available in pharmacies nationwide and samples are available via a "by request" sample program. In April 2003, a generic equivalent to the Company's Tiazac was introduced into the market, resulting in a decrease in sales of \$34,604,000 for the quarter and \$69,915,000 for the nine months. The Company has ceased all promotional efforts for Tiazac as of September 2003 and expects further declines in sales of its Tiazac brand as generic substitution rates continue to increase. During the June 2003 quarter, the Company introduced its own generic version of Tiazac. Sales of that product in the December 2003 quarter were \$6,395,000 and for the nine months were \$28,838,000, including initial stocking. The remainder of the net sales change for the three and nine months was due principally to volume declines.

Other income for the three and nine months ended December 31, 2003 decreased over the same periods of last year as the prior year included capital gains on the liquidation of certain long-term investments, a gain on the sale of assets and interest on tax refunds. Interest income also decreased as the Company received lower rates of return on invested funds during the current periods.

Cost of sales as a percentage of net sales for the three and nine-month periods ended December 31, 2003 was 23%, unchanged from the same periods last year.

Selling, general and administrative expenses increased \$30,706,000 and \$73,422,000 for the three and nine-month periods ended December 31, 2003, respectively, as compared to the same periods last year. During the December quarter, the Company received marketing approval for both its GAD indication for Lexapro and for Namenda to treat moderate to severe Alzheimer's disease. To effectively market these products, the Company added 500 additional representatives to its salesforce during the current quarter. The GAD indication for Lexapro was launched in January 2004 and Namenda will be launched on March 1, 2004. This latest salesforce expansion brings the total number of representatives and managers to approximately 2,800. The cost of the expanded salesforce, including initial hiring and training costs, together with promotional costs, will result in an increase in selling, general and administrative expenses for the remainder of the year.

Research and development expense decreased by \$1,305,000 for the quarter and increased \$12,277,000 for the nine months ended December 31, 2003. The nine-month period included a one-time write-off of the dexloxiplumide license after its phase III clinical program for the treatment of IBS failed to achieve statistically significant results. The Company continues to conduct clinical trials for additional indications for Lexapro. In May 2003, a supplemental New Drug Application (sNDA) was filed to expand Lexapro's labeling to include panic disorder. In October 2003, the Company received FDA approval to market Namenda for the treatment of moderate to severe Alzheimer's disease. Namenda is also being studied for the treatment of mild to moderate Alzheimer's disease as well as an additional indication for neuropathic pain. Based on positive results of a Phase III study released on January 7, 2004, Forest plans to file an sNDA for the treatment of mild to moderate Alzheimer's disease. Other products currently in our pipeline for which clinical studies are being conducted include: neramexane, a follow-on NMDA receptor antagonist to Namenda, which is currently in Phase II clinical trials and is being tested for various CNS disorders; Aerospan® for asthma and oxycodone/ibuprofen for moderate to severe pain, both of which received approvable letters and remain under review with the FDA. Forest received an approvable letter from the FDA in August 2002 regarding lercanidipine for the treatment of hypertension. In December 2002, the FDA indicated that it would require the Company to conduct additional clinical trials in order to approve the dosing regimen requested by Forest. The Company is presently re-formulating lercanidipine and developing a clinical program to support the requested dosing regimen. During fiscal 2003, the FDA determined that the NDA for acamprosate, licensed from Merck Santé S.A.S. for the treatment of alcohol dependence, was non-approvable. Subsequently, the FDA agreed to accept a resubmission of the NDA with a re-analysis of existing safety and efficacy data. Merck Santé submitted the re-analyzed data in December 2003 and is in the process of submitting additional information to completely respond to the FDA's

non-approvable letter. On January 9, 2004, Forest announced that it had entered into an agreement with Cypress Bioscience, Inc. and Pierre Fabre Medicament for the development and marketing of milnacipran, which is currently being evaluated for the treatment of Fibromyalgia Syndrome (FMS), a frequent cause of chronic, widespread pain and is estimated to affect six to twelve million people in the United States. There are currently no products approved for the treatment of FMS. The Company anticipates further increases in research and development for the remainder of this fiscal year and beyond.

The effective income tax rate declined to 21% in the quarter and nine months ended December 31, 2003, as compared to 24% from the same period last year. The lower effective tax rate was a direct result of the increase in the proportion of earnings generated in lower taxed foreign jurisdictions versus the United States. These earnings include manufacturing income and development expenses of our operations in Ireland, which are taxed at 10% through 2010 and at 12.5% thereafter.

The Company expects to continue its profitability during the current fiscal year with continued growth in its principal promoted products.

Inflation has not had a material effect on the Company's operations for the periods presented.

Forward Looking Statements

Except for the historical information contained herein, the Management Discussion and other portions of this Form 10-Q contain forward looking statements that involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products and the risk factors listed from time to time in the Company's filings with the SEC, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2003.

Quantitative and Qualitative Disclosures About Market Risk

In the normal course of business, operations of the Company may be exposed to fluctuations in currency values and interest rates. These fluctuations can vary the costs of financing, investing and operating transactions. Because the Company had no debt and only minimal foreign currency transactions, there was no material impact on earnings due to fluctuations in interest and currency exchange rates.

Controls and Procedures

As of the end of the period covered by this report, the Company conducted an evaluation, under the supervision and with the participation of the principal executive officer and principal financial officer, of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on this evaluation, the principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms. There was no change in the Company's internal control over financial reporting during the Company's most recently completed fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

Edgar Filing: FOREST LABORATORIES INC - Form 10-Q

Reference is hereby made to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2003 and to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2003, for a description of certain legal proceedings to which the Company is a party.

The Company has received a subpoena from the Office of the Inspector General of the Federal Office of Personnel Management requesting documents related to Celexa, a prescription medication approved for the treatment of depression. The subpoena primarily requests documents related to the marketing of Celexa and educational and promotional programs with physicians. The Company believes that other makers of pharmaceutical products for the treatment of CNS indications have received subpoenas from this office. The Office of Personnel Management is the Federal Government's human resources agency. The Company is cooperating in responding to the subpoena.

Item 6. Exhibits and Reports on Form 8-K

- (a) Exhibit 31.1 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 31.2 Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- Exhibit 32.2 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- (b) Reports on Form 8-K. On October 14, 2003 the Company furnished a current report on Form 8-K to file its earnings press release for the quarter ended September 30, 2003.

SIGNATURES

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

Date: February 13, 2004

Forest Laboratories, Inc.

(Registrant)

/s/ Howard Solomon

Howard Solomon
Chairman of the Board,
Chief Executive Officer
and Director

/s/ John E. Eggers

John E. Eggers
Vice President - Finance and
Chief Financial Officer