

FOREST LABORATORIES INC
Form 10-Q
August 09, 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 June 30, 2004

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 X 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 August 9, 2004:
370,275,535.

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Condensed Consolidated Balance Sheets

(In thousands)	June 30, 2004 <u>(Unaudited)</u>	<u>March 31, 2004</u>
<u>Assets</u>		
Current assets:		
Cash (including cash equivalent investments of \$1,730,349 in June and \$1,724,942 in March)	\$1,733,229	\$1,726,558
Marketable securities	80,928	66,064
Accounts receivable, less allowance for doubtful accounts of \$20,803 in June and \$20,762 in March	263,139	287,618
Inventories, net	581,232	610,182
Deferred income taxes	159,293	205,071
Other current assets	<u>40,659</u>	<u>20,741</u>
Total current assets	<u>2,858,480</u>	<u>2,916,234</u>
Marketable securities	<u>571,618</u>	<u>337,890</u>
Property, plant and equipment	426,600	404,082
Less: accumulated depreciation	<u>111,666</u>	<u>106,125</u>
	<u>314,934</u>	<u>297,957</u>
Other assets:		
Goodwill	14,965	14,965

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License agreements, product rights and other intangibles, less accumulated amortization of \$252,728 in June and \$245,921 in March	267,908	274,835
Deferred income taxes	16,291	16,387
Other	<u>1,127</u>	<u>4,468</u>
 Total other assets	 <u>300,291</u>	 <u>310,655</u>
 Total assets	 \$4,045,323 =====	 \$3,862,736 =====

See notes to condensed consolidated financial statements.

FOREST LABORATORIES, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets

(In thousands, except for par values)	June 30, 2004 <u>(Unaudited)</u>	<u>March 31, 2004</u>
<u>Liabilities and Stockholders' Equity</u>		
Current liabilities:		
Accounts payable	\$ 157,028	\$ 159,798
Accrued expenses	327,336	321,564
Income taxes payable	<u>66,199</u>	<u>123,392</u>
 Total current liabilities	 <u>550,563</u>	 <u>604,754</u>
 Deferred income taxes	 <u>1,765</u>	 <u>2,118</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 405,712 shares in June and 405,144 shares in March	40,571	40,514
Additional paid-in capital	862,495	846,297

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Retained earnings	2,885,853	2,655,934
Accumulated other comprehensive income	2,252	10,324
Treasury stock, at cost (35,632 shares in June and 35,617 shares in March)	(<u>298,176</u>)	(<u>297,205</u>)
Total stockholders' equity	<u>3,492,995</u>	<u>3,255,864</u>
Total liabilities and stockholders' equity	\$4,045,323 =====	\$3,862,736 =====

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	
	June 30,	
	<u>2004</u>	<u>2003</u>
Net sales	\$782,396	\$605,748
Other income	<u>10,430</u>	<u>8,681</u>
	<u>792,826</u>	<u>614,429</u>
Costs and expenses:		
Cost of sales	177,201	140,668
Selling, general and administrative	239,305	191,494
Research and development	<u>85,283</u>	<u>53,347</u>
	<u>501,789</u>	<u>385,509</u>
Income before income tax expense	291,037	228,920

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Income tax expense	<u>61,118</u>	<u>49,103</u>
Net income	\$229,919	\$179,817
	=====	=====
Net income per common and common equivalent share:		
Basic	\$0.62	\$0.49
	=====	=====
Diluted	\$0.60	\$0.48
	=====	=====
Weighted average number of common and common equivalent shares outstanding:		
Basic	369,796	364,098
	=====	=====
Diluted	380,943	376,803
	=====	=====

See notes to condensed consolidated financial statements.

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

(In thousands)	Three Months Ended	
	<u>June 30,</u>	
	<u>2004</u>	<u>2003</u>
Net income	\$229,919	\$179,817
Other comprehensive income (loss)	(8,072)	<u>4,563</u>
Comprehensive income	\$221,847	\$184,380
	=====	=====

See notes to condensed consolidated financial statements.

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

(In thousands)	Three Months Ended June 30,	
	2004	2003
Cash flows from operating activities:		
Net income	\$ 229,919	\$ 179,817
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation	6,242	5,255
Amortization and impairments	6,807	5,754
Deferred income tax expense (benefit)	2,033	(4,604)
Foreign currency translation loss		237
Tax benefit realized from the exercise of stock options by employees	49,445	22,764
Net change in operating assets and liabilities:		
Decrease (increase) in:		
Accounts receivable, net	24,479	(33,176)
Inventories, net	28,950	(20,501)
Other current assets	(19,918)	(12,317)
Increase (decrease) in:		
Accounts payable	(2,770)	(76,254)
Accrued expenses	5,772	14,366
Income taxes payable	(57,193)	(1,969)
Decrease in other assets	<u>3,341</u>	<u>630</u>
Net cash provided by operating activities	<u>277,107</u>	<u>80,002</u>
Cash flows from investing activities:		
Purchase of property, plant and equipment, net	(23,327)	(18,262)
Purchase of marketable securities	(292,178)	(234,754)
Redemption of marketable securities	43,585	203,770
Purchase of license agreements, product rights and other intangibles	<u> </u>	<u>(5,000)</u>

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Net cash used in investing activities	(<u>271,920</u>)	(<u>54,246</u>)
Cash flows from financing activities:		
Net proceeds from common stock options exercised by employees under stock option plans	<u>9,327</u>	<u>12,319</u>
Effect of exchange rate changes on cash	(<u>7,843</u>)	<u>4,022</u>
Increase in cash and cash equivalents	6,671	42,097
Cash and cash equivalents, beginning of period	<u>1,726,558</u>	<u>1,265,508</u>
Cash and cash equivalents, end of period	\$1,733,229 =====	\$1,307,605 =====
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Income taxes	\$66,976	\$32,843

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 three-month period ended June 30, 2004 are not necessarily indicative of the results that may be expected for the year ending March 31, 2005. For further information refer to the consolidated financial

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statements and footnotes thereto incorporated by reference in the Company's Annual Report on Form 10-K for the year ended March 31, 2004.

2. Inventories:

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

(In thousands)	June 30, 2004 <u>(Unaudited)</u>	<u>March 31, 2004</u>
Raw materials	\$359,749	\$359,075
Work in process	22,352	40,982
Finished goods	<u>199,131</u>	<u>210,125</u>
	\$581,232	\$610,182
	=====	=====

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 June 30,</u>	
	<u>2004</u>	<u>2003</u>
Basic	369,796	364,098
Effect of assumed conversion of employee stock options and warrants	<u>11,147</u>	<u>12,705</u>
Diluted	380,943	376,803
	=====	=====

Options to purchase approximately 125,400 shares of common stock at an exercise price of \$76.66 per share that were outstanding during a portion of the three-month period ended June 30, 2004 were not included in the computation of diluted net income per share because they were anti-dilutive. Options to purchase approximately 229,300 shares of common stock at an exercise price of \$53.23 per share that were outstanding during a portion of the three-month period ended June 30, 2003 were not included in the computation of diluted net income per share because they were anti-dilutive. These options expire through 2014.

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.

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-month periods ended June 30, 2004 and June 30, 2003: dividend yield of zero; expected volatility of 26.31% and 41.87%, respectively; risk-free interest rate of 4.5%; 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)	Three Months Ended	
	<u>June 30,</u>	
	<u>2004</u>	<u>2003</u>
Net income:		
As reported	\$229,919	\$179,817
Deduct: Total stock-based employee compensation expense determined under fair value method	(<u>8,604</u>)	(<u>8,423</u>)
Pro forma	\$221,315	\$171,394
	=====	=====
Net income per common share:		
Basic:		
As reported	\$0.62	\$0.49
Pro forma	\$0.60	\$0.47
Diluted:		
As reported	\$0.60	\$0.48
Pro forma	\$0.58	\$0.45

FOREST LABORATORIES, INC. AND SUBSIDIARIES

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

The Company posted record revenues for the quarter ended June 30, 2004, which will be discussed further in Results of Operations. During the quarter, the Company entered into an agreement for the marketing and development of a novel drug for the treatment of acute ischemic stroke.

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 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 is 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 future cash flows 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 decreased by \$3,563,000 from March 31, 2004 because of a shift from short-term to long-term marketable securities to receive more favorable rates of return. In total, cash and marketable securities increased by \$255,263,000. Accounts receivable decreased both in the number of days outstanding and in total as extended dating terms offered to customers for initial orders of Namenda, which remained in accounts receivable at the end of March, were paid in the current quarter. During the quarter, finished goods inventory decreased as did work in process inventory. The decrease in both was due to the fact that finished goods inventory for our antidepressant franchise was being maintained at higher levels in previous periods until such time that the predictability of Lexapro® and Celexa® sales was established. The Company has reduced finished goods inventory for both products to appropriate levels. Decreases in deferred taxes and income taxes payable were due to the utilization of the tax benefit from the exercise of stock options by employees.

Property, plant and equipment increased primarily due to 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 expanding its packaging and distribution facility, which will add approximately 185,000 square feet to that location. The Company also purchased a 40,000 square foot facility in St. Louis which will be used for office and administration. 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. During the

quarter, the Company also made a technology investment to expand its principal operating systems to include salesforce and warehouse management applications.

The Company recently announced that its Board of Directors has approved a share repurchase program for up to 20 million shares of its common stock. The authorization became effective July 22, 2004, and the program has no set expiration date. The Company expects to make repurchases from time to time in the open market depending on market conditions.

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 or companies, capital investments and the share repurchase program.

Results of Operations

Net sales increased \$176,648,000 to \$782,396,000, a 29% increase from the same period last year, primarily due to the continued success of the antidepressant franchise, particularly Lexapro. Lexapro, which surpassed Celexa as the Company's largest product with sales of \$363,872,000 as compared to Celexa sales of \$261,053,000, contributed \$172,880,000 to the net sales change. At the end of the quarter, Lexapro had achieved a 17.2% share of total prescriptions in the SSRI market, while Celexa's share declined to 8.5% from a peak share of 17.5% in August 2002. As anticipated, a portion of Lexapro's market share has come from Celexa which resulted in a Celexa sales decline of \$23,664,000 from the same period last year primarily due to volume. The Company anticipates further volume declines in Celexa sales and continued growth of Lexapro sales. The Company also anticipates that a generic version of Celexa will be approved by the FDA some time this fiscal year and will at that time launch its own generic version while continuing to detail the advantages of upgrading patients to Lexapro. Sales of Namenda®, an NMDA receptor antagonist for the treatment of moderate to severe Alzheimer's disease, launched in March 2004, amounted to \$57,368,000 for the current quarter. Tiazac® sales declined by \$26,469,000 during the quarter as compared to the same period last year due to generic competition. The Company ceased all promotional efforts for Tiazac as of September 2003 and expects further declines in sales as generic substitution rates continue to rise. The remainder of the net sales change for the period was due principally to volume declines on the Company's older non-promoted product lines.

Other income for the current quarter increased over the same period last year primarily as a result of higher interest income from increases in funds available for investment. During the quarter the Company continued the shift of its investments to longer term (maturity dates do not exceed two years) in order to receive more favorable rates of return.

Cost of sales as a percentage of net sales was 23% during the current quarter, unchanged from the same period last year.

Selling, general and administrative expenses increased \$47,811,000 during the current quarter as compared to the same period last year due primarily to marketing and sales activities associated with the launch of Namenda. To effectively market Namenda, the Company added approximately 525 representatives to its salesforce during the third quarter of fiscal 2004. This latest salesforce expansion brought the total number of representatives and managers to approximately 2,825.

Research and development expense increased \$31,936,000 during the current quarter as compared to the same period last year. The majority of the increase was due to a license payment made pursuant to an agreement with PAION GmbH for the development and marketing of desmoteplase, a novel drug currently in phase II studies for the treatment of acute ischemic stroke. The remainder of the increase was from costs associated with ongoing clinical trials and staff increases and associated costs required to support currently marketed products and products in various stages of development.

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- The Company continues to conduct clinical trials for additional indications for Lexapro. In May 2004, a supplemental New Drug Application ("sNDA") was filed to expand Lexapro's labeling to include the treatment of social phobia.
- 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 from a Phase III study released in January 2004, Forest plans to file an sNDA for the treatment of mild to moderate Alzheimer's disease around the end of the second quarter of fiscal 2005.
- Neramexane, a follow-on NMDA receptor antagonist to Namenda, is currently in Phase II clinical trials and is being tested for various CNS disorders.
- The Company 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. The Company has reformulated lercanidipine and has begun a clinical program to support the requested dosing regimen.
- On July 29, 2004, the FDA approved the NDA for acamprosate, licensed from Merck KGaA for the treatment of alcohol dependence. The Company expects to commercially launch the product towards the end of fiscal 2005 under the trade name Campral®.
- During the fourth quarter of fiscal 2004, the Company entered into two licensing agreements; the first with Cypress Bioscience, Inc. for the development and marketing of milnacipran, which is currently in Phase III development as a treatment for Fibromyalgia Syndrome. The second was a development agreement with ChemoCentryx, Inc. for novel therapeutics for autoimmune and inflammatory diseases. The most advanced compound in the research program may be ready to enter Phase I clinical studies within the next 12 months.

The Company anticipates further increases in research and development for the remainder of this fiscal year and beyond.

The effective income tax rate was 21% during the current quarter, unchanged from the same period last year. The 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 and development income from 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, 2004.

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

By letter dated June 28, 2004, the Company was requested by the Office of the Attorney General of the State of New York to provide the Office of the Attorney General with documents relating to reports of clinical trials of the Company's products for "off-label" uses of such products. The letter indicates that the Office of the Attorney General "is concerned that Forest Labs may have violated . . . laws by failing to disclose to New York physicians and consumers clinical trial data in Forest Labs' control concerning Celexa and other pharmaceutical products . . ." The Company believes it has complied with all applicable laws relating to such disclosures and is cooperating with the document request.

Reference is hereby made to the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2004 for a description of certain other legal proceedings to which the Company is a party.

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 April 20, 2004 the Company furnished a current report on Form 8-K to file its earnings press release for the quarter and year ended March 31, 2004.

SIGNATURES

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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: August 9, 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