FOREST LABORATORIES INC Form 10-Q August 08, 2005

#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-Q**

(Mark One)

# [X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended June 30, 2005

# [ ] 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.

(I.R.S. Employer

(*Zip code*)

*Identification Number)* 

(Exact name of registrant as specified in its charter)

Delaware

11-1798614

(State or other jurisdiction of incorporation or organization)

909 Third Avenue New York, New York

10022-4731

(Address of principal executive offices)

(212) 421-7850

(*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 <u>X</u> No <u>.</u>.

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

Number of shares outstanding of Registrant's Common Stock as of August 8, 2005: 339,889,008.

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#### PART I - FINANCIAL INFORMATION

#### FOREST LABORATORIES, INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets

(In thousands)	June 30, 2005 (Unaudited)	March 31, 2005
Assets		
Current assets: Cash (including cash equivalent investments of \$1,080,550 in June and \$1,145,987 in March)		\$1,165,498
	\$1,094,657	
Marketable securities	546,834	453,747
Accounts receivable, less allowance for doubtful accounts of \$20,762 in June and \$20,773 in March	304,565	323,129
Inventories	627,798	613,903
Deferred income taxes	140,579	131,596
Other current assets	40,072	20,149
Total current assets	_2,754,505	_2.708.022
Marketable securities	<u>    189.980</u>	351,635
Property, plant and equipment	501,748	492,752
Less: accumulated depreciation	137,135	130,724
	364,613	362,028

Other assets:		
Goodwill	14,965	14,965
License agreements, product rights and other intangibles, less accumulated amortization		
of \$288,073 in June and \$277,135 in March		263,370
	251,814	
Deferred income taxes	3,230	3,723
Other	1,175	1,259
Total other assets	271,184	283,317
Total assets	\$3,580,282 ======	\$3,705,002 ======

See notes to condensed consolidated financial statements.

## FOREST LABORATORIES, INC. AND SUBSIDIARIES Condensed Consolidated Balance Sheets

(In thousands, except for par values)	June 30, 2005 (Unaudited)	March 31, 2005
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 169,484	\$ 228,016
Accrued expenses	264,231	257,912
Income taxes payable	84,767	77,762
Total current liabilities	518,482	<u> </u>
Deferred income taxes	8,345	8,927

Stockholders' equity:

Series preferred stock, \$1.00 par; shares authorized 1,000;

no shares issued or outstanding		
Common stock, \$.10 par; shares authorized 1,000,000; issued		
407,751 shares in June and 407,234 shares in March	40,775	40,723
Additional paid-in capital	915,991	893,864
Retained earnings	3,711,316	3,494,739
Accumulated other comprehensive income	2,774	9,028
Treasury stock, at cost		
(68,074 shares in June and 59,591 shares in March)	( <u>1,617,401</u> )	( <u>1,305,969</u> )
Total stockholders' equity	3,053,455	3,132,385
Total liabilities and stockholders' equity	\$3,580,282	\$3,705,002
Total habilities and stockholders equity	$\psi 5,500,202$	$\psi_{3}, 103, 002$

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,	
	2005	2004
Net sales	\$674,653	\$782,396
Contract revenue	26,269	2,252
Other income	10,844	8,178
	<u>711,766</u>	<u>    792,826</u>
Costs and expenses:		
Cost of sales	158,846	177,201
Selling, general and administrative	268,473	239,305
Research and development	56,393	85,283
	483,712	501,789

Income before income tax expense	228,054	291,037
Income tax expense	11,477	61,118
Net income	\$216,577	\$229,919
Net income per common and common equivalent share:		
Basic	\$0.63	\$0.62
Diluted	==== \$0.62	==== \$0.60
Weighted average number of common and common equivalent shares outstanding:	====	
Basic	343,107	369,796
	======	
Diluted	348,043	380,943
	=	=

See notes to condensed consolidated financial statements.

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

(In thousands)	Three Mo	
	2005	2004
Net income	\$216,577	\$229,919
Other comprehensive loss	( <u>6,254</u> )	( <u>8.072</u> )
Comprehensive income	\$210,323	\$221,847
	=======	

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,	
	_	2005	2004
Cash flows from operating activities:			
Net income	\$	216,577	\$ 229,919
Adjustments to reconcile net income to			
net cash provided by operating activities:			
Depreciation		7,090	6,242
Amortization and impairments		10,938	6,807
Deferred income tax expense (benefit)	(	2,479)	2,033
Foreign currency translation loss		908	
Tax benefit realized from the exercise of stock options by employees		6,298	49,445
Net change in operating assets and liabilities:			
Decrease (increase) in:			
Accounts receivable, net		18,564	24,479
Inventories	(	13,895)	28,950
Other current assets	(	19,923)	( 19,918)
Increase (decrease) in:			
Accounts payable	(	58,532)	( 2,770)
Accrued expenses		6,319	5,772
Income taxes payable		7,005	( 57,193)
Decrease in other assets	_	84	3,341
Net cash provided by operating activities	-	178.954	277,107
Cash flows from investing activities:			
Purchase of property, plant and equipment, net	(	10,305)	( 23,327)
Purchase of marketable securities	(	67,873)	( 292,178)
Redemption of marketable securities		136,441	80,359

Purchase of license agreements, product rights and other intangibles Net cash provided by (used in) investing activities	58.263	( <u>235,146</u> )
Cash flows from financing activities: Net proceeds from common stock options exercised by employees under stock option plans Purchase of treasury stock	8,818 9. ( <u>310,962</u> )	.327
Net cash provided by (used in) financing activities	( 302,144)	9,327
Effect of exchange rate changes on cash	(5,914)	( <u>7,843</u> )
Increase (decrease) in cash and cash equivalents Cash and cash equivalents, beginning of period	( 70,841) <u>1,165,498</u>	43,445 _ <u>1,091,635</u>
Cash and cash equivalents, end of period	\$1,094,657	\$1,135,080 =======
Supplemental disclosures of cash flow information:		
Cash paid during the period for: Income taxes	\$652	\$66,976

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, 2005 are not necessarily indicative of the results that may be expected for the year ending March 31, 2006. 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, 2005.

#### 2. Accounts Receivable:

Accounts receivable, net, consists of the following:

	June 30, 2005	
(In thousands)	(Unaudited)	March 31, 2005
Trade	\$270,481	\$267,938
Other	34,084	55,191
	\$304,565	\$323,129
	======	

#### 3. Inventories:

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

	June 30, 2005	
(In thousands)	(Unaudited)	March 31, 2005
Raw materials	\$345,938	\$304,745
Work in process	8,104	10,507
Finished goods	273,756	298,651
	\$627,798	\$613,903

#### 4. Net Income Per Share:

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

(In thousands)		Three Months Ended June 30,	
	2005	2004	
Basic	343,107	369,796	
Effect of assumed conversion of employee stock options and warrants	4,936	11,147	

#### Diluted

# 348,043 380,943

Options to purchase approximately 11,951,000 shares of common stock at exercise prices ranging from \$37.86 to \$76.66 per share that were outstanding during a portion of the three-month period ended June 30, 2005 were not included in the computation of diluted net income per share because they were anti-dilutive. 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. These options expire through 2015.

5. 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, 2005 and June 30, 2004: dividend yield of zero; expected volatility of 27.74% and 26.31%, respectively; risk-free interest rates of 4.0% and 4.5%, respectively; 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:

	Three Months Ended		
(In thousands, except per share data)	June 30,		
	2005	2004	
Net income:			
As reported	\$216,577	\$229,919	
Deduct: Total stock-based employee compensation expense			
determined under fair value method	( <u>7,698</u> )	( <u>8,604</u> )	
Pro forma	\$208,879	\$221,315	
Net income per common share:			
Basic:			
As reported	\$0.63	\$0.62	
Pro forma	\$0.61	\$0.60	
Diluted:			
As reported	\$0.62	\$0.60	
Pro forma	\$0.60	\$0.58	

In December 2004, the Financial Accounting Standards Board (the FASB) issued Statement of Financial Accounting Standards No.123 (revised 2004), "Share-Based Payment" (SFAS 123R) which is a revision of SFAS 123, "Accounting for Stock-Based Compensation". SFAS 123R supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" and requires companies to expense the estimated fair value of employee stock options as well as other types of share-based compensation. The Company is required to adopt the provisions of SFAS 123R in its 2007 fiscal year, although earlier adoption is permitted. The Company is currently evaluating a plan of implementation, and expects that the financial statement impact of adoption will approximate the pro forma impact presented above.

#### 6. Business Segment Information:

The Company operates in only one segment. Below is a breakdown of net sales by therapeutic class:

(In thousands)	Three Months Ended June 30,	
	2005	2004
Central nervous system (CNS)	\$579,931	\$682,293
Cardiovascular	17,686	27,571
Other	77,036	72,532
	\$674,653	\$782,396

#### FOREST LABORATORIES, INC. AND SUBSIDIARIES MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS (Dollar amounts in thousands)

The decline in revenues for the quarter ended June 2005 as compared with June 2004, resulted from the loss of Celexa® sales to generic competition. Sales of Celexa were \$261,053 in the June 2004 quarter compared with \$4,155 in the current period for both the brand and generic combined. Offsetting this reduction in revenue was strong growth in Lexapro® and Namenda® sales, as well as co-promotion income earned on Benicar®. We had not earned any co-promotion income in the June 2004 quarter.

During the quarter, we received the results of a recently completed placebo-controlled proof of concept study of neramexane in the treatment of moderate to severe Alzheimer's disease. The study showed sufficient clinical activity, safety and tolerability for us to continue development of the compound. In July 2005, we received a non-approvable letter from the Food and Drug Administration (FDA) in response to our supplemental New Drug Application (sNDA) to expand the indication of Namenda to include mild Alzheimer's disease. The FDA accepted the sNDA for review in November 2004. Upon completing its review, the FDA acknowledged that it had informed us that a single positive study in patients with mild to moderate Alzheimer's disease would be adequate to support extending Namenda's claim to include mild patients. The FDA further acknowledged that the six-month, U.S. mild to moderate study which reached statistical significance at the required primary endpoints was such a study. Nevertheless, the FDA decided not to approve Namenda for mild patients with mild to moderate Alzheimer's disease - a study of Namenda monotherapy conducted by H. Lundbeck A/S in Europe and a combination study conducted by Forest in the U.S. with Namenda administered to patients already taking an acetylcholinesterase inhibitor. In both of these studies, which were included in the sNDA filing, Namenda performed numerically better than placebo; however, statistical

significance was not reached at the primary endpoints. In all three studies, Namenda was found to be well tolerated. We plan to meet with the FDA shortly to further discuss the non-approvable letter.

During fiscal 2005, our Board of Directors authorized a share repurchase program for up to 30 million shares of common stock (the 2005 Repurchase Program), of which approximately 6,100,000 shares remained to be purchased during the current fiscal year. As of May 11, 2005, all of these shares were repurchased, completing the program. In May 2005, our Board of Directors authorized a new share repurchase program for up to 25 million shares of common stock (the 2006 Repurchase Program). As of June 30, 2005, 2,400,000 shares have been repurchased under this program and we continue to have authority to purchase up to an additional 22,600,000 shares.

During the fourth quarter of fiscal 2005, we repatriated \$1,238,900 in qualifying dividends pursuant to the American Jobs Creation Act of 2004. We intend to utilize the repatriated funds pursuant to a qualified domestic investment plan which we have adopted. This repatriation was the maximum dividend amount allowed and resulted in a one-time tax charge of \$90,657. In the current quarter, we reversed \$36,414 of this charge based on recently issued U.S. Treasury Department guidance. The originally enacted law did not specifically address whether the deduction applied to the required tax gross-up related to the dividend. In May 2005, the U.S. Treasury Department clarified that the dividend received deduction does in fact apply to the tax gross-up amount and accordingly we were allowed to reverse the \$36,414 million in the current quarter. The impact of such reversal, was to increase our diluted earnings per share in the June quarter by \$0.10 per share.

#### Financial Condition and Liquidity

Net current assets increased by \$91,691 during the current period from March 31, 2005. During the current quarter, approximately 6.1 million shares of common stock were repurchased pursuant to the 2005 Repurchase Program authorized by our Board of Directors in fiscal 2005, at various prices totaling \$217,146, completing that program. In May 2005, our Board of Directors approved the 2006 Repurchase Program, which authorized the repurchase of up to 25 million additional shares. In order to fund these share repurchase programs, as longer term investments matured they are being used either to fund the purchase of common stock or shifted to shorter term investments, in anticipation of further common stock repurchases. During the current quarter, the share repurchase programs were funded with cash generated from normal operating activities and supplemented by maturing investments. As of June 30, 2005 we had repurchased 2.4 million shares pursuant to the 2006 Repurchase Program at various prices totaling \$93,816 and we continue to have authorization to purchase an additional 22.6 million shares under this program. In total, cash and marketable securities - both short-term and long-term - decreased by \$139,409 during the current period. Trade accounts receivable increased due to strong sales of our principal branded products, partially offset by lower sales of Celexa due to generic competition, while other accounts receivable decreased due to a payment from Sankyo Pharma for our co-promotion of Benicar. The increase in raw materials was primarily due to increased levels of Lexapro inventory to meet higher demand. Work in process and finished goods inventories decreased during the period primarily due to Lexapro and Namenda, as wholesalers brought their inventories to more normal levels approximately two and a half to three weeks as compared with the two weeks they were holding at March 31, 2005. We believe that our inventory levels are adequate to support future demand. Other current assets increased due principally to the renewal of our insurance policies, particularly product liability insurance, which are paid in full at the time of renewal and expensed over the course of the year. The changes in accounts payable, particularly the timing of raw material receipts and payments, and accrued expenses were due to normal ongoing operating activities.

Property, plant and equipment increased primarily due to the continuing expansion of our facilities in order to meet future product demands. In Jersey City, we are leasing an additional floor of office space totaling 36,000 square feet to accommodate growth in our Research Institute. On Long Island, we are adding 37,000 square feet to our sales training facility. In fiscal 2005 we purchased a 40,000 square foot facility in St. Louis, which is being used as a data center and we have begun construction on a 141,000 square foot addition to our current distribution facility, which will bring the total capacity of our warehouse and distribution center to approximately 475,000 square feet. In Ireland, we are refurbishing a 90,000 square foot plant which will provide redundancy for the manufacture of Lexapro and Namenda

and additional capacity for future products. Further property expansions and acquisitions are planned in the future to meet the needs from increased sales and related production, warehousing and distribution, sales training and for products under development. During the current quarter, we also continued to make technology investments to expand our principal operating systems to include salesforce and warehouse management applications.

During fiscal 2005 our Board of Directors approved the 2005 Repurchase Program which authorized the purchase of up to 30 million shares of common stock. We purchased 23,930,400 shares on the open market at an average price of \$42.06 per share during fiscal 2005, and completed the balance of the program in May 2005. The remainder of the shares were purchased at an average price of \$35.79, bringing the total cost of the 30 million shares to \$1,224,192. On May 10, 2005 our Board of Directors authorized the 2006 Repurchase Program for up to 25 million shares. As of June 30, 2005, 2,400,000 shares have been repurchased under this program and we continue to have authority to purchase up to an additional 22,600,000 shares. We expect to make additional purchases, 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, payment of achieved milestones, capital investments and the 2006 Repurchase Program.

### **Results of Operations**

Net sales decreased \$107,743 to \$674,653, a 14% decrease from the same period last year, primarily due to generic competition for Celexa. Sales of Celexa were \$261,053 in the June 2004 quarter compared with \$4,155 in the current period for both the brand and generic combined. Offsetting the losses from Celexa were strong sales of Lexapro and Namenda. Lexapro, our largest product, with sales of \$461,072, contributed \$97,200 to the net sales change, of which \$78,108 was due to volume and \$19,092 was due to price. As of June 30, 2005 Lexapro achieved a 20.0% share of total prescriptions in the selective serotonin reuptake inhibitor (SSRI) market. Lexapro has patent protection until 2009 and we have applied for an extension to 2012. In fiscal 2004, we received notification from generic manufacturers that they had filed an Abbreviated New Drug Application (ANDA) with a Paragraph IV Certification with the FDA for a generic equivalent to Lexapro. We believe that our patents on Lexapro are valid. Forest has commenced an action for patent infringement against the third party ANDA filers with a trial date in December 2005.

Sales of Namenda, an N-methyl-D-aspartate (NMDA) receptor antagonist for the treatment of moderate to severe Alzheimer's disease, launched in March 2004, increased \$57,336 as compared to the same period last year to \$114,704 for the current quarter. Namenda is the first product indicated for the treatment of moderate to severe Alzheimer's disease and has generated significant new prescriptions in the retail and long-term care markets. Namenda achieved a 27.3% share of total prescriptions in the Alzheimer's market as of June 30, 2005. In July 2005, we received a non-approvable letter from the FDA in response to our sNDA to expand the indication of Namenda to include mild Alzheimer's disease - a study of Namenda monotherapy conducted by H. Lundbeck A/S in Europe and a combination study conducted by Forest in the U.S. with Namenda administered to patients already taking an acetylcholinesterase inhibitor. In both of these studies, which were included in the sNDA filing, Namenda performed numerically better than placebo; however, statistical significance was not reached at the primary endpoints. In all three studies, Namenda was found to be well tolerated. We plan to meet with the FDA shortly to further discuss the non-approvable letter. We anticipate Namenda continuing positive growth through fiscal 2006.

Sales of Campral<sup>®</sup>, which was launched in the fourth quarter of fiscal 2005, amounted to \$4,324. Campral is indicated for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. Sales of Combunox<sup>TM</sup>, also launched in the fourth quarter of fiscal 2005, amounted to \$58. Combunox, which is for the treatment of acute, moderate to severe pain, had a slower than anticipated uptake at launch due its status as a schedule II controlled substance which initially hinders retail stocking at the pharmacy level. Tiazac<sup>®</sup> sales declined \$9,885 from last year due primarily to generic competition. The remainder of the net sales change for the period was due principally to volume fluctuations of our older non-promoted product lines.

Contract revenue for the current quarter was \$26,269 compared to \$2,252 in the same period last year primarily due to co-promotion income from our co-marketing agreement with Sankyo Pharma for Benicar of \$24,267. Under the terms of the agreement, Forest has been co-promoting Benicar since May 2003 and is entitled to a share of the product profits (as defined) from the point the product becomes cumulatively profitable. Benicar became cumulatively profitable during the second quarter of fiscal 2005.

Other income for the current quarter increased over the same period last year primarily due to higher interest income received on funds available for investment resulting from more favorable rates of return.

Cost of sales as a percentage of net sales increased to 23.54% for the current quarter as compared to 22.65% for the same period last year, primarily due to product mix, particularly the mix between branded and generic Tiazac.

Selling, general and administrative expenses increased \$29,168 in the current quarter as compared to the same period last year due in large measure to the activities of our salesforce and additional product license amortization expense on our recently launched products.

Research and development expense decreased \$28,890 in the current quarter primarily due to the payment to PAION GmbH in the same period last year for the U.S. and Canadian rights to desmoteplase, a compound being investigated for the treatment of acute ischemic stroke. Research and development expense also reflects the following developments:

- During the quarter, we received the results of a recently completed placebo-controlled proof of concept study of neramexane in the treatment of moderate to severe Alzheimer's disease. The study showed sufficient clinical activity, safety and tolerability for us to continue development of the compound.
- In July 2005, we received a non-approvable letter from the FDA in response to our sNDA to expand the indication of Namenda to include mild Alzheimer's disease. The FDA accepted the sNDA for review in November 2004. Upon completing its review, the FDA acknowledged that it had informed us that a single positive study in patients with mild to moderate Alzheimer's disease would be adequate to support extending Namenda's claim to include mild patients. The FDA further acknowledged that the six-month, U.S. mild to moderate study which reached statistical significance at the required primary endpoints was such a study. Nevertheless, the FDA decided not to approve Namenda for mild patients based upon this single positive study in light of two previously disclosed, additional studies of Namenda in patients with mild to moderate Alzheimer's disease a study of Namenda monotherapy conducted by H. Lundbeck A/S in Europe and a combination study conducted by Forest in the U.S. with Namenda administered to patients already taking an acetylcholinesterase inhibitor. In both of these studies, which were included in the sNDA filing, Namenda performed numerically better than placebo; however, statistical significance was not reached at the primary endpoints. In all three studies, Namenda was found to be well tolerated. We plan to meet with the FDA shortly to further discuss the non-approvable letter.
- In November 2004, Forest reported on the development progress of lercanidipine, a calcium channel blocker (CCB), being investigated for the treatment of hypertension. In August 2002, an approvable letter was received from the FDA seeking additional data related to the proposed dosing regimen. In response to the request, we conducted an eight week Phase II pilot study in order to assess the clinical efficacy profile of lercanidipine in a new modified release formulation. The preliminary study results indicated that this modified release version of lercanidipine was associated with a clinically relevant reduction in blood pressure, but did not meet all the pre-set criteria for dose response across the range of doses studied. Lercanidipine treatment was well tolerated in this study. We are evaluating additional alternative extended release formulations and considering future development activities.

- During the third quarter of fiscal 2005, Forest entered into a collaboration agreement with Gedeon Richter Limited for the North American rights to RGH-188, a compound which is being developed for the treatment of schizophrenia, bipolar mania and other psychiatric conditions.
- During the second quarter of fiscal 2005, Forest entered into a collaboration agreement with Glenmark Pharmaceuticals S.A. for the North American development and marketing of GRC 3886, a PDE4 inhibitor which will be developed for the treatment of asthma and COPD. In March 2005, as a result of a successfully completed Phase I single and multiple dose study in the U.K., a milestone payment was made to Glenmark pursuant to the terms of the collaboration agreement.
- During the first quarter of fiscal 2005, we entered into an agreement with PAION GmbH for the development and marketing of desmoteplase, a novel drug currently in Phase III clinical studies for the treatment of acute ischemic stroke.
- During the fourth quarter of fiscal 2004, Forest 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. We expect to have the results of the first Phase III study of milnacipran in fibromyalgia patients in late September 2005. The second was a development agreement with ChemoCentryx, Inc. for novel therapeutics for autoimmune and inflammatory diseases.

The effective tax rate decreased to 5% in the current quarter as compared to 21% in the same period last year primarily due to a one-time reversal of \$36,414 related to the March 2005 charge of \$90,657 for the repatriation of dividends pursuant to the American Jobs Creation Act of 2004. Excluding this impact, the effective tax rate would have been 21% and is lower than the U.S. statutory tax rate due to 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.

On October 22, 2004, the American Jobs Creation Act of 2004 (the Act) was signed into law. The Act contains numerous changes to existing tax laws, including both domestic and foreign tax incentives. One of the key provisions of the Act, new Internal Revenue Code Section 965, includes a temporary incentive for U.S. multinationals to repatriate foreign earnings by providing an elective 85% dividends received deduction for certain cash dividends from controlled foreign corporations. The provision is effective for dividends paid during the taxable year beginning before the date of enactment or the first taxable year beginning on or after the date of enactment. Moreover, the dividends must be invested in the United States under a domestic reinvestment plan approved by senior management and, subsequently, the board of directors. The provision contains a non-exclusive list of examples of permitted uses of the funds which include funding of worker hiring and training, infrastructure, research and development, capital investment and the financial stabilization of the corporation for purposes of job retention and creation. The dividends subject to the dividend received deduction must not exceed the greater of \$500,000 or the earnings reported on the company's financial statements pursuant to Accounting Principles Board Opinion No. 23 as permanently invested earnings for financial statements certified on or before June 30, 2003. Forest, upon satisfying the U.S. investment criteria and other requirements under the Act, as well as evaluating the guidance provided by the U.S. Treasury Department, executed such a qualifying repatriation in the amount of \$1,238,900, the maximum dividend amount for which the special deduction under the Act may be claimed. The resulting additional U.S. tax of \$90,657 with respect to such repatriation was provided for in our fiscal 2005 income tax expense. In the current quarter, we reversed \$36,414 of this accrual based on recently issued U.S. Treasury Department guidance. Since the originally enacted law did not specifically address whether the deduction applied to the required tax gross-up related to the dividend as of the date the financial statements were prepared for the March 2005 quarter, Forest accrued the tax assuming the deduction did not apply which represented an additional \$36 million of tax. In May the U.S. Treasury Department clarified that the dividend received deduction does in fact apply to the tax gross-up amount and accordingly we were allowed to reverse the \$36 million in the current quarter.

We expect to continue our profitability in the current fiscal year with continued growth in our principal promoted products.

Inflation has not had a material effect on our operations for the periods presented.

#### Critical Accounting Policies

The following accounting policies are important in understanding our financial condition and results of operations and should be considered an integral part of the financial review. Refer to the notes to the consolidated financial statements for additional policies.

#### Estimates and Assumptions

The preparation of financial statements in conformity with generally accepted accounting principles requires us 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. Forest 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. We review all significant estimates affecting the financial statements on a recurring basis and record the effect of any adjustments when necessary. Certain of these risks, uncertainties and assumptions are discussed further under the section entitled "Forward Looking Statements".

#### Revenue Recognition

Revenues are recorded in the period the merchandise is shipped. As is typical in the pharmaceutical industry, gross product sales are subject to a variety of deductions, primarily representing rebates and discounts to government agencies, wholesalers and managed care organizations. These deductions represent estimates of the related liabilities and, as such, judgment is required when estimating the impact of these sales deductions on gross sales for a reporting period. If estimates are not representative of actual settlement, results could be materially affected. 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, including third party data, 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 rate. 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 are recorded when customer credits are issued or payments are made to third parties.

The sensitivity of estimates can vary by program and type of customer. However, estimates associated with Medicaid and contract rebates are most at risk for adjustment because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can range up to one year. Because of this time lag, in any given quarter, adjustments to actual may incorporate revisions of prior quarters.

Provisions for Medicaid and contract rebates during a period are recorded based upon the actual historical experience ratio of rebates paid and actual prescriptions written. The experience ratio is applied to the period's sales to determine the rebate accrual and related expense. This experience ratio is evaluated regularly to ensure that the historical trends are as current as practicable. As appropriate, we will adjust the ratio to more closely match the current experience or expected future experience. In assessing this ratio, we consider current contract terms, such as the effect of changes in formulary status, discount rate and utilization trends. Periodically, the accrual is adjusted based upon actual payments made for rebates. If the ratio is not indicative of future experience, results could be affected. Rebate accruals for

Medicaid were \$52,729 at June 30, 2005 and \$58,026 at June 30, 2004. Commercial discounts and other rebate accruals were \$53,902 at June 30, 2005 and \$103,733 at June 30, 2004. These and other rebate accruals are established in the period the related revenue was recognized, resulting in a reduction to sales and the establishment of a liability, which is included in accrued expenses.

The following table summarizes the quarterly activity in the accounts related to accrued rebates, sales returns and discounts (*In thousands*):

	June 30, 2005	June 30, 2004
Beginning balance	\$171,119	\$266,209
Provision for rebates Settlements	56,818 ( <u>61,233</u> ) ( 4,415)	50,380 ( <u>74,233</u> ) ( 23,853)
Provision for returns Settlements	6,540 ( <u>7,601</u> ) ( <u>1,061</u> )	8,599 ( <u>6,950</u> ) 1,649
Provision for chargebacks and discounts Settlements	106,890 ( <u>101,571</u> ) 5,319	95,465 ( <u>95,503</u> ) ( <u>38</u> )
Ending balance	\$170,962	\$243,967

Deductions for chargebacks (primarily discounts to group purchasing organizations and federal government agencies) closely approximate actual as these deductions are settled generally within 2-3 weeks of incurring the liability.

Forest's policy relating to the supply of inventory at wholesalers is to maintain stocking levels of up to three weeks and to keep monthly levels consistent from year to year, based on patterns of utilization. We have historically closely monitored wholesale customer stocking levels by purchasing information directly from customers and by obtaining other third party information. Unusual or unexpected variations in buying patterns or utilizations are investigated.

Sales incentives are generally given in connection with a new product launch. These sales incentives are recorded as a reduction of revenues and are based on terms fixed at the time goods are shipped. New product launches may result in expected temporary increases in wholesaler inventories, which as described above, are closely monitored and have not resulted in increased product returns.

#### 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 our filings with the SEC, including the Annual Report on Form 10-K for the fiscal year ended March 31, 2005.

#### Quantitative and Qualitative Disclosures About Market Risk

In the normal course of business, operations may be exposed to fluctuations in currency values and interest rates. These fluctuations can vary the costs of financing, investing and operating transactions. Because we 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 during the company's most recently completed fiscal reporting.

#### Part II - Other Information

#### Item 1. Legal Proceedings

Reference is hereby made to our Annual Report on Form 10-K for the fiscal year ended March 31, 2005 for a description of certain legal proceedings to which we are a party.

#### Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Purchase of equity securities by Forest:

In July 2004, our Board of Directors approved the repurchase of up to 20,000,000 shares of our outstanding Common Stock (2005 Repurchase Program) which was increased to 30,000,000 shares in December 2004. Under the 2005 Repurchase Program we repurchased the shares from time-to-time at prevailing prices and as permitted by applicable securities laws (including SEC Rule 10b-18) and New York Stock Exchange requirements, and subject to market conditions. The first purchase under the 2005 Repurchase Program occurred on September 9, 2004. As of May 11, 2005, we had completed the repurchase of the 30,000,000 shares authorized under the 2005 Repurchase Program.

On May 10, 2005 our Board of Directors authorized a new share repurchase program (2006 Repurchase Program) for up to 25,000,000 shares of our Common Stock. The authorization became effective immediately and has no set expiration date. We expect to make the repurchases from time to time on the open market, depending on market conditions and as permitted by applicable securities laws (including SEC Rule 10b-18) and New York Stock Exchange requirements. As of June 30, 2005, 2,400,000 shares have been repurchased and we continue to have authority to purchase up to an additional 22,600,000 shares under the 2006 Repurchase Program.

The following table summarizes the repurchase of Common Stock under both the 2005 Repurchase Program and the 2006 Repurchase Program during the first quarter of the fiscal year covered by this report:

Period	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the program
4/1/05 through 4/30/05	3,958,800	\$35.62	3,958,800	2,110,800 (1)
5/1/05 through 5/31/05	2,110,800	\$36.07	2,110,800	25,000,000 (2)
6/1/05 through 6/30/05	2,400,000	\$39.09	2,400,000	22,600,000 (3)

(1) Represents shares available for repurchase under the 2005 Repurchase Program.

(2) Represents shares available for repurchase under the 2006 Repurchase Program. As of May 11, 2005, there were no shares available for repurchase under the 2005 Repurchase Program.

(3) Represents shares available for repurchase under the 2006 Repurchase Program.

#### Item 6. Exhibits

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

#### 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: August 8, 2005

#### Forest Laboratories, Inc.

(Registrant)

/s/ Howard Solomon

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

/s/ Francis I. Perier, Jr.

Francis I. Perier, Jr. Senior Vice President - Finance and Chief Financial Officer