EON LABS INC
Form 10-Q
November 09, 2004

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

or

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

Commission File Number 001-31333

For the quarterly period ended September 30, 2004

Eon Labs, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**13-3653818**
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification Number)

11413

227-15 North Conduit Avenue
Laurelton, New York
(Address of Principal Executive Offices) (Zip Code)

(718) 276-8600
(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant (1) has filed all reports required 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 ý No o

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ý No o

As of November 8, 2004, there were 88,823,124 shares of the Registrant s Common Stock, $0.01 par value per share, outstanding.

Eon Labs, Inc. and Subsidiaries
Table of Contents

PART I FINANCIAL INFORMATION

Eon Labs, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(dollars in thousands, except per share amounts)

	September 30, 2004 (Unaudited)	December 31, 2003
Assets		
Current assets		
Cash and cash equivalents	$ 52,110	$ 43,852
Investments	161,663	115,281
Accounts receivable, net	72,438	35,678
Inventories	68,502	56,441
Deferred tax assets, net	55,775	56,439
Prepaid expenses and other current assets	23,027	8,096
Total current assets	433,515	315,787
Property, plant and equipment, net	52,307	50,409
Goodwill	46,934	46,934
Other intangible assets, net	23,187	26,007
Other assets	5,702	2,408
Total assets	$ 561,645	$ 441,545
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 13,942	$ 13,612
Accrued liabilities	124,790	89,226
Total current liabilities	138,732	102,838
Long-term liabilities		
Deferred tax liabilities, net	9,136	9,136
Deferred revenue	37	200
Other	699	591
Total liabilities	148,604	112,765
Contingencies (Notes 8 and 9)		
Stockholders equity		

Common stock, par value $.01 per share; 100,000,000 shares authorized; 88,982,924 and 88,723,824 shares issued; 88,821,024 and 88,599,624 shares outstanding at September 30, 2004 and December 31, 2003, respectively		890		888
Preferred stock, par value $.01 per share; 5,000,000 shares authorized; none issued				
Additional paid-in capital		192,943		194,507
Retained earnings		224,861		135,774
Accumulated other comprehensive (loss) income		(41)		5
		418,653		331,174
Less:Unearned deferred stock-based compensation		(46)		(184)
Treasury stock, at cost, 161,900 and 124,200 shares at September 30, 2004 and December 31, 2003, respectively		(5,566)		(2,210)
Total stockholders equity		413,041		328,780
Total liabilities and stockholders equity	$	561,645	$	441,545

The accompanying notes are an integral part of these condensed consolidated financial statements.

Eon Labs, Inc. and Subsidiaries

Condensed Consolidated Statements of Income

(dollars in thousands, except per share amounts) (unaudited)

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	**2003**	**2004**	**2003**
Net sales	$ 109,778	$ 85,011	$ 320,969	$ 234,549
Cost of sales	50,187	38,376	137,144	109,782
Gross profit	59,591	46,635	183,825	124,767
Operating expenses				
Selling, general and administrative	10,832	10,698	36,183	24,751
Research and development	6,031	6,612	18,290	15,934
Total operating expenses	16,863	17,310	54,473	40,685
Operating income	42,728	29,325	129,352	84,082
Other income (expense), net				
Interest income	617	337	1,550	1,001
Interest expense				(300)
Other income, net		37	13,046	148
Total other income, net	617	374	14,596	849
Income before provision for income taxes	43,345	29,699	143,948	84,931
Provision for income taxes	(15,256)	(11,880)	(54,754)	(33,973)
Net income	$ 28,089	$ 17,819	$ 89,194	$ 50,958
Net income per common share				
Basic	$ 0.32	$ 0.20	$ 1.00	$ 0.58
Diluted	$ 0.31	$ 0.20	$ 0.98	$ 0.56
Weighted average common shares outstanding				
Basic	88,782,745	88,606,832	88,754,770	88,443,078
Diluted	90,583,501	90,508,282	90,729,710	90,482,958

The accompanying notes are an integral part of these condensed consolidated financial statements.

Eon Labs, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(dollars in thousands) (unaudited)

	For the nine months ended September 30,	
	2004	**2003**
Cash flows from operating activities		
Net income	$ 89,194	$ 50,958
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for accounts receivable allowances	1,961	19,666
Depreciation and amortization	7,831	6,705
Deferred income taxes	664	
Deferred compensation	138	336
Amortization of deferred revenue	(163)	(173)
Amortization of discount on note payable		269
Tax benefit from exercises of stock options	5,337	3,145
Changes in assets and liabilities:		
Accounts receivable	(38,721)	(11,295)
Inventories	(12,061)	(15,919)
Prepaid expenses and other current assets	(14,995)	(16,765)
Other assets		(175)
Accounts payable	330	876
Accrued liabilities	35,641	25,888
Net cash provided by operating activities	75,156	63,516
Cash flows from investing activities		
Capital expenditures	(10,203)	(8,302)
Net purchases of short-term investments	(46,581)	(63,922)
Net cash used in investing activities	(56,784)	(72,224)
Cash flows from financing activities		
Payment on seller note		(4,799)
Decrease in restricted cash	64	59
Proceeds from exercises of stock options	936	499
Purchase of treasury shares	(11,191)	(2,596)
Net cash used in financing activities	(10,191)	(6,837)
Effect of exchange rate changes on cash and cash equivalents	77	
Net increase (decrease) in cash and cash equivalents	8,258	(15,545)
Cash and cash equivalents at beginning of period	43,852	62,323
Cash and cash equivalents at end of period	$ 52,110	$ 46,778

The accompanying notes are an integral part of these condensed consolidated financial statements.

Eon Labs, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

(dollars in thousands, except per share amounts) (unaudited)

1. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by Eon Labs, Inc. and its subsidiaries (the Company) without audit pursuant to the rules and regulations of the United States Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying unaudited condensed consolidated financial statements reflect all adjustments (consisting only of normal recurring accruals) necessary for a fair presentation of the Company s financial position as of September 30, 2004 and results of its operations and cash flows for the periods presented. The consolidated balances as of December 31, 2003 were derived from audited financial statements but do not include all disclosures required by generally accepted accounting principles. The accompanying condensed consolidated financial statements have been prepared in accordance with accounting standards for interim financial statements and should be read in conjunction with the Company s audited consolidated financial statements and the notes thereto for the year ended December 31, 2003. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the year.

Revenue Recognition

Sales are recognized when the products are received by the customer, which represents the point when the risks and rewards of ownership are transferred to the customer. Discounts, rebates and contract pricing adjustments are recorded as a reduction of sales based on agreed upon terms with the Company s customers at the time of sale. The Company calculates a reserve for discounts and rebates based upon actual sales under such arrangements. Reserves for contract pricing adjustments represent the difference between the prices wholesalers are billed by the Company and the contract prices billed by wholesalers to their customers. In determining a reserve for contract pricing adjustments, the Company takes into account an estimate of the percentage of product sales subject to such pricing adjustments based on historical trends. Historical trends are adjusted for new product introductions and changes in wholesaler or contract prices.

Accounts receivable is presented net of allowances for discounts, rebates, contract pricing adjustments and doubtful accounts, which were $96,617 and $94,656 at September 30, 2004 and December 31, 2003, respectively.

Shelf stock adjustments are provided following a reduction in the prices of the Company s products due to the competitive environment. Such adjustments are credited to the Company s customers based on their on-hand inventory quantities. Reserves are generally established when the Company reduces its prices.

Estimates for returns, which are recorded at the time of sale, relate primarily to returns of expiring products. The Company utilizes historical trends to estimate the amount of products to be returned due to product expiration.

Accrued liabilities include $107,996 and $73,086 for returns, promotional incentives and Medicaid rebates at September 30, 2004 and December 31, 2003, respectively. During the three months ended September 30, 2004, the Company recorded an adjustment to reduce its reserve accrual related to promotions by $1,760. This reduction was attributed to certain promotional programs in the final stages of their program lives and for which an accrual was no longer considered necessary.

Shipping and Handling Costs

The Company classifies shipping and handling costs as part of selling, general and administrative expenses. Shipping and handling costs were $1,303 and $1,219 for the three months ended September 30, 2004 and 2003, respectively, and $3,940 and $3,434 for the nine months ended September 30, 2004 and 2003, respectively.

Investments

The Company invests in publicly traded debt securities which are categorized as securities available-for-sale and are carried at fair value. Unrealized gains and losses related to such securities, net of taxes, are excluded from operating results and reported as accumulated other comprehensive income/loss in the Stockholders Equity section of the balance sheet. The Company periodically evaluates declines in the value of its investments to determine if such declines are other-than-temporary and thus the investment is impaired. A variety of factors are considered when determining whether declines are other-than-temporary, including, among others, the financial condition of the investee, the length of time and magnitude of the decline, and the Company s ability and intent to hold the investment.

The book value of such securities exceeded market value by $192 at September 30, 2004 and $391 at June 30, 2004. The market value of such securities exceeded book value by $23 and $61 at September 30, 2003 and June 30, 2003, respectively.

The book value of such securities exceeded market value by $192 at September 30, 2004, while the market value of such securities exceeded book value by $7 at December 31, 2003. The market value of such securities exceeded book value by $23 and $73 at September 30, 2003 and December 31, 2002, respectively.

Comprehensive Income

Statement of Financial Accounting Standard (SFAS) No. 130, Reporting Comprehensive Income, requires reporting and displaying comprehensive income and its components, which for the Company includes net income, unrealized gains and losses, net of tax, on

available-for-sale securities and foreign currency translation gains and losses. Total comprehensive income was $28,323 and $89,148 for the three and nine month periods ended September 30, 2004, respectively, and $17,796 and $50,929 for the three and nine month periods ended September 30, 2003, respectively. In accordance with SFAS No. 130, the accumulated unrealized gains (losses) on available-for-sale

securities and gains (losses) on foreign currency translation are shown as a separate component of stockholders equity.

Other Income

Other income for the nine months ended September 30, 2004 includes the receipt of a $3,000 bond from GlaxoSmithKline (Glaxo) to settle all patent infringement litigation related to the Company s Bupropion HCl, ER 100 mg and 150 mg tablets, and the receipt of a $10,000 settlement from Glaxo, in exchange for agreeing to the dismissal of the Company s complaint against Glaxo for malicious prosecution of an earlier suit against the Company, which claimed the Company s Nabumetone product infringed Glaxo s patent. See Note 8.

Reclassifications

Amortization of other intangibles of $940 for each of the quarters and $2,820 for the nine months ended September 30, 2004 and 2003, respectively, previously included in selling, general and administrative expenses has been reclassified to cost of sales for all periods. In addition, other amounts have been reclassified to conform to the current period presentation.

2. Stockholders Equity

Stock Split

On June 1, 2004, Eon distributed approximately 44.5 million additional shares of common stock in order to effect a 2-for-1 stock split declared in May. The stock split was effected in the form of a 100% stock dividend for stockholders of record at the close of business on May 17, 2004. All share, per share data and December 31, 2003 equity amounts have been retroactively restated to reflect the impact of the stock split.

Additional Paid-In Capital

Additional paid-in capital decreased by $1,564 to $192,943 at September 30, 2004 from $194,507 at December 31, 2003. The decrease is the result of the reissuance of $7,835 of treasury shares offset by $934 of proceeds from the exercise of employee stock options and $5,337 of tax benefits associated with these exercise transactions.

Stock Options

During the nine months ended September 30, 2004, options to purchase 610,000 shares of common stock at an average exercise price of $29.24 per share were granted. The stock options granted are exercisable for up to ten years following the date of the grant. Except for 60,000 options, which vested immediately, the options vest and become exercisable at the rate of 20% per year.

During the nine months ended September 30, 2004, 573,160 options with a weighted-average exercise price of $1.63 were exercised and 31,200 options were cancelled.

Deferred Stock-Based Compensation

The Company amortized deferred stock compensation in the amount of $46 and $112 for the three months ended September 30, 2004 and 2003, respectively, and $138 and $336 for the nine months ended September 30, 2004 and 2003, respectively.

Stock-Based Compensation

The Company has adopted SFAS No. 123 Accounting for Stock-Based Compensation. SFAS No. 123 allows companies which have stock-based compensation arrangements with employees to adopt a new fair-value basis of accounting for stock options and other equity instruments, or to continue to apply the existing accounting required by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees. The Company intends to continue to account for stock-based compensation arrangements under APB Opinion No. 25 and related interpretations in accounting for its stock-based compensation. The Company recognizes no compensation expense with respect to stock options if the exercise price equals or exceeds the fair value of the underlying security on the date of grant and other terms are fixed. The Company has also adopted the disclosure provisions of SFAS No. 148 Accounting for Stock-Based Compensation - Transition and Disclosure. This pronouncement requires prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reporting results as determined through the use of the Black-Scholes option-pricing model. The additional required disclosures are found below.

The fair value of the options was determined using the Black-Scholes option-pricing model with the following assumptions:

	September 30, 2004	**September 30, 2003**
Dividend yield	0%	0%
Volatility	45%	45%
Risk-free interest rate	3.41%	3.53%
Expected life	5 years	5 years

A reconciliation of the Company s net earnings to pro forma net earnings and the related pro forma earnings per share amounts for the three months and nine months ended September 30, 2004 and 2003 is provided below. For purposes of pro forma disclosure, stock-based compensation expense is recognized in accordance with the provisions of SFAS No. 123.

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	2003	2004	2003
Net income, as reported	$ 28,089	$ 17,819	$ 89,194	$ 50,958
Add: Compensation expenses included in net income, net of related tax effect	28	67	84	202
Less: Adjustment to net income for pro forma stock-based compensation expenses, net of related tax effect	(587)	(187)	(2,091)	(440)
Pro forma net income	$ 27,530	$ 17,699	$ 87,187	$ 50,720
As reported net earnings per share:				
Basic	$ 0.32	$ 0.20	$ 1.00	$ 0.58
Diluted	$ 0.31	$ 0.20	$ 0.98	$ 0.56
Pro forma net earnings per share:				
Basic	$ 0.31	$ 0.20	$ 0.98	$ 0.57
Diluted	$ 0.30	$ 0.20	$ 0.96	$ 0.56

Stock Repurchase Program

In April 2003, the Company s Board of Directors approved the repurchase of up to 600,000 shares of the Company s common stock. In July 2003, the Company adopted a plan to repurchase up to 250,000 shares through December 31, 2003. In February 2004, the Company adopted a plan to repurchase up to 187,500 shares through March 31, 2004. In April 2004, the Company adopted a plan to repurchase up to 187,500 shares through June 30, 2004. Depending on market conditions, the Company also expects to conduct purchases in the open market and in privately negotiated transactions from time to time during its normal trading window and may enter into future plans to repurchase shares. The repurchased shares have been accounted for as treasury shares and will be used to offset potential dilution from the exercise of outstanding stock options.

During the nine months ended September 30, 2004, in accordance with these plans, the Company repurchased 351,760 shares of its outstanding common stock at an average price of $31.81 per share totaling $11,191. These transactions are accounted for under the cost method.

3. Net Income Per Common Share

Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding for the period. Diluted earnings per share reflects the potential dilution of stock options. Details of the calculations are as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	2003	2004	2003
Net income per share-basic:				
Net income	$ 28,089	$ 17,819	$ 89,194	$ 50,958
Weighted average shares outstanding-basic	88,782,745	88,606,832	88,754,770	88,443,078
Net income per share-basic	$ 0.32	$ 0.20	$ 1.00	$ 0.58
Net income per share-diluted:				
Net income	$ 28,089	$ 17,819	$ 89,194	$ 50,958
Weighted average shares outstanding-basic	88,782,745	88,606,832	88,754,770	88,443,078
Dilutive effect of stock options	1,800,756	1,901,450	1,974,940	2,039,880
Weighted average shares-diluted	90,583,501	90,508,282	90,729,710	90,482,958
Net income per share-diluted	$ 0.31	$ 0.20	$ 0.98	$ 0.56

Excluded from this earnings per share calculation are options to purchase 600,000 shares, as their impact would be anti-dilutive for the three months ended September 30, 2004.

4. Adoption of New Accounting Pronouncements

In January 2003, the FASB issued Interpretation (Fin) No. 46, Consolidation of Variable Interest Entities (as revised by Fin No. 46R). This interpretation, as revised, provides guidance with respect to the consolidation of certain entities, referred to as variable interest entities (VIEs), in which an investor is subject to a majority of the risk of loss from the VIE s activities, or is entitled to receive a majority of the VIE s residual returns. This interpretation also provides guidance with respect to the disclosure of VIEs in which an investor maintains an interest, but is not required to consolidate. The provisions of the interpretation are effective immediately for all VIEs created after January 31, 2003, or in which the Company obtains an interest after that date. For VIEs created before February 1, 2003, the provisions are effective July 1, 2003. In November 2003, the Company invested $1,150 for 50% ownership in an entity formed to provide research and development services for the Company as well as third parties. It has been determined that such investee is deemed a VIE, which has been consolidated in the Company s financial statements. The net assets and result of operations of this entity were not material to the Company in 2004. Creditors, or beneficial interest holders, of the consolidated VIE have no recourse to the general credit of the Company.

The American Jobs Creation Act of 2004 (the Act) was signed into law in October 2004 and has several provisions for manufacturing companies, including a deduction related to qualified production activities taxable income. Under the Act, qualified production activities include the Company s manufacturing of pharmaceutical products.

The FASB is currently reviewing the impact of the qualified production activities deduction on deferred taxes and is expected to issue guidance in the fourth quarter of 2004. Until this guidance is issued, the impact on the Company cannot be determined.

Effective September 30, 2004, the Company adopted Emerging Issues Task Force No. 03-1 (EITF 03-1), The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments . EITF 03-1 is applicable to the Company s debt securities within the scope of SFAS No. 115 that are classified as available for sale. EITF 03-1 provides guidance as to when an investment is considered impaired, whether the impairment is other-than-temporary and determining the amount of the impairment loss. The guidance also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The adoption of EITF 03-1 did not have a material impact on the Company s financial condition and results of operations. In accordance with EITF 03-1, the Company will adopt the disclosure provisions for its annual financial statements.

5. Inventories

Inventories consist of the following:

	September 30, 2004	December 31, 2003
Raw material	$ 30,646	$ 24,745
Work-in-process	8,974	7,529
Finished goods	28,882	24,167
	$ 68,502	$ 56,441

6. Line of Credit

On February 8, 2002, the Company entered into a three-year $25 million credit agreement, which was amended and restated on July 30, 2004, extending the term of the agreement to December 31, 2007 and eliminating a security interest in the Company s accounts receivable and inventories. Interest on any borrowing under the line will accrue at the rate of interest equal to either the adjusted LIBOR rate plus 1.5%, the prime rate or the fixed rate (as set by the bank). The rate will depend upon the terms of the selected borrowings. The agreement has covenants which require the maintenance of certain financial ratios, including leverage, consolidated debt and minimum consolidate net worth, as further described therein. At September 30, 2004 and December 31, 2003, there were no borrowings under the credit agreeement.

7. Transactions Between the Company and Related Parties

The following is a summary of the Company s related-party transactions:

	For the three months ended September 30,		For the nine months ended September 30,	
	2004	2003	2004	2003
Net sales to subsidiaries of Hexal AG	$ 685	$ 321	$ 1,733	$ 483
Purchases of products and supplies from subsidiaries of Hexal AG		713	1,345	1,031
Hexal AG reimbursement to the Company for expenditures that were made on Hexal AG s behalf			574	
Company s reimbursement to Hexal AG for expenditures that were made on the Company s behalf			90	27
Company s expenditures made on behalf of Santo Holding (Deutschland) GmbH	58		58	
Cyclosporine agreements with Hexal AG(1)	872	1,670	3,229	4,801
Fees incurred under product development agreements with Hexal AG	500	1,300	1,216	1,300

(1) Under agreements with Hexal AG, the Company pays Hexal AG based on sales of specific products, which were developed using Hexal AG s patented technology.

At September 30, 2004 and December 31, 2003, the Company had a payable to Hexal AG of approximately $1,440 and $1,102, respectively, included in accrued liabilities.

At September 30, 2004 and December 31, 2003, the Company had receivables from subsidiaries of Hexal AG of approximately $534 and $120, respectively, included in prepaid expenses and other current assets.

At September 30, 2004 and December 31, 2003, the Company had a receivable from Santo Holding (Deutschland) GmbH of approximately $58 and $0, respectively, which is included in accrued liabilities.

8. Litigation

Product Liability Litigation

Fen-phen Litigation

Since May 1997, the Company and certain of its customers have been named as defendants in numerous product liability lawsuits, some of which are class actions, filed in various state and federal courts in connection with its manufacture of Phentermine Hydrochloride. These lawsuits typically name as a defendant Wyeth (formerly American Home Products Corporation), the manufacturer of two anti-obesity drugs, Fenfluramine and Dexfenfluramine, and also name manufacturers, distributors and retailers of Phentermine. Fenfluramine and Phentermine were prescribed in combination in an off-label use commonly called fen-phen, while Dexfenfluramine was generally prescribed alone, but occasionally in combination with Phentermine. In September 1997, the manufacturer of Fenfluramine and Dexfenfluramine agreed with the U.S. Food and Drug Administration (the FDA) to voluntarily withdraw both products from the market. The FDA has not requested that Phentermine be withdrawn from the market.

The plaintiffs in these cases (the fen-phen cases) typically allege that the short- and long-term use of Fenfluramine in combination with Phentermine causes, among other things, primary pulmonary hypertension, valvular heart disease and/or neurological dysfunction. Some lawsuits allege emotional distress caused by the purported increased risk of injury in the future. Plaintiffs typically seek relief in the form of monetary damages (including economic losses, medical care and monitoring expenses, loss of earnings and earnings capacity, other compensatory damages and punitive damages), generally in unspecified amounts, on behalf of the individual or the class. Some actions

seeking class certification ask for certain types of equitable relief, including, but not limited to, declaratory judgments and the establishment of a research program or medical surveillance fund. Certain companies that distributed or sold the Company s Phentermine and are named as defendants in certain of these lawsuits seek a defense and indemnity from the Company.

During 2000, the United States District Court for the Eastern District of Pennsylvania, the federal court before which all federal cases were consolidated for discovery, found that proposed anti-Phentermine causation testimony by two expert witnesses was not supported by scientific evidence and thus would be barred. These two experts were the only national anti-Phentermine causation experts identified in the consolidated federal litigation, and were to have been generic experts in hundreds of cases. The Court s decision to curb their testimony substantially has resulted in many cases being dismissed. To date, there has been no scientific testimony accepted by any court that establishes a connection between the use of Phentermine, either alone or in combination with Fenfluramine and/or Dexfenfluramine, and the allegations of injury made by plaintiffs in these lawsuits.

In late 1999, Wyeth, the major defendant in the fen-phen litigation and the former manufacturer of both Fenfluramine and Dexfenfluramine, announced a proposed settlement of all fen-phen claims against it nationwide (excepting only claims for certain serious medical conditions). The United States District Court for the Eastern District of Pennsylvania, which supervises discovery of all federal fen-phen cases in a consolidated multidistrict litigation, certified a nationwide settlement class and approved the proposed settlement, which became final in January 2002. This settlement has reduced the number of new cases in which the Company and its distributors have been named as defendants.

As of September 30, 2004, the Company had been named and served in over 7,000 fen-phen product liability cases. Approximately 91% of these cases have been dismissed, and the Company remains a defendant in approximately 626 pending fen-phen cases. Since the beginning of the fen-phen litigation, only one case has gone to trial with the Company and its distributors as defendants. In that instance, the case against the Company and all the Phentermine defendants, including other Phentermine manufacturers and distributors, was dismissed on motion before the presentation of any evidence.

While the number of lawsuits being filed has decreased substantially, the Company expects additional, similar lawsuits to be filed. The Company and its outside counsel believe that the Company has substantial defenses to these claims, though the ultimate outcome cannot be determined. As of September 30, 2004, there had been no finding of liability for fen-phen injury against the Company and no payment by the Company to settle any combination-related fen-phen lawsuit. No provision for any related liability has been reflected in the Company s financial statements.

Phentermine Litigation

The Company has been named as a defendant in several cases in which the plaintiffs allege injury from the use of Phentermine alone, and in one instance the Company was named as a third-party defendant in a medical malpractice case in which negligent prescription of Phentermine was alleged. A number of these claims have been dismissed in the Company s favor, and as of September 30, 2004, only one such claim remains pending.

Because discovery has not been completed in this pending case, predicting the ultimate outcome of this action is not possible, and no provision for any related liability has been reflected in the Company s financial statements. The Company believes it has substantial defenses to this claim.

Net sales of Phentermine by the Company for were approximately $4,494 and $7,834 for the nine months ended September 30, 2004 and 2003, respectively, and $1,537 and $2,984 for the three months ended September 30, 2004 and 2003, respectively.

Defense/Indemnity Issues Related to Fen-phen and Phentermine Litigation

In or about April 2000, the Company exhausted its product liability insurance covering all combination-related Phentermine lawsuits and any non-combination Phentermine lawsuits resulting from claims regarding the ingestion of Phentermine prior to June 1998. Since that time, the Company has funded its own defense in such lawsuits. However, pursuant to an October 1999 settlement with an insurance carrier, the Company has made insurance coverage claims for fen-phen claims filed on or after June 22, 2003, which allege fen-phen use prior to June 1998. The Company reached an agreement with its insurer regarding these insurance claims and has received $1,400, which will be used to defray the future cost of the Company s fen-phen defense. Additionally, the Company agreed to fund or partially fund the defense of certain of its distributors and to indemnify them, provided certain conditions are met. Furthermore, the Company has reached favorable defense/indemnity agreements with several retailers of the Company s Phentermine products. Fen-phen and Phentermine litigation defense costs, and the costs of related defense agreements, are being expensed as incurred.

Other Product Liability Litigation

The Company has been named as a defendant in several other product liability lawsuits in which plaintiffs allege that Company-manufactured pharmaceuticals containing phenylpropanolamine (PPA) caused injury. PPA was removed from the market in 2000 at the FDA s request after a study appeared to show a potentially increased risk of hemorrhagic stroke in certain patient cohorts. The Company previously manufactured two low-volume prescription products that contained PPA that were discontinued in 1999 and 2000.

To date, the Company has been named in five lawsuits alleging injury or wrongful death from the use of Company-manufactured pharmaceuticals containing PPA. As of September 30, 2004, all but two PPA cases against the Company had been dismissed or discontinued. Discovery in these lawsuits is incomplete, and predicting the ultimate outcome of these actions is not possible. The Company believes its product liability insurance is adequate to cover existing PPA claims and, consequently, no provision for any related liability has been reflected in the Company s financial statements.

In April 2004, the Company was also named as a defendant in a lawsuit alleging injury from the use of Company-manufactured Desipramine, which has been settled for nominal value. In May 2004, the Company was also named defendant in a product liability lawsuit in which the plaintiff alleges injury from the use of Company-manufactured Lisinopril-HCTZ. Discovery in this case continues, and the Company believes it would be premature to express a judgment as to its outcome. Finally, a lawsuit filed against the Company in 2003 alleging injury from the use of Company-manufactured Amiodarone was settled in July 2004 for nominal value.

Patent Infringement Litigation

In August 2000, Novartis Pharmaceuticals Corporation (Novartis) filed a complaint in the United States District Court for the District of Delaware alleging, among other things, that the Company s generic Cyclosporine product infringes a patent owned by Novartis. In December 2002, the United States District Court for the District of Delaware granted the Company s motion for summary judgment of non-infringement of the patent. In April 2004, the United States Court of Appeals for the Federal Circuit affirmed the judgment of the Delaware district court that the Company s generic Cyclosporine product does not infringe Novartis patent. Novartis request for a rehearing by the United States Appeals Court is still pending. The Company s potential liability and expenses in this matter are not covered by insurance. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows, and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

In January 2001, Apotex, Inc. (Apotex) filed an action in the United States District Court for the Eastern District of New York alleging that by manufacturing, selling and offering to sell Cyclosporine capsules the Company is infringing a patent of which Apotex alleges it is the exclusive licensee. Apotex seeks injunctive relief as well as an unspecified amount of damages and has also asserted a claim that the alleged infringement was willful, that the case is therefore exceptional and that Apotex should therefore be awarded the attorney fees it has incurred and treble damages in the action. The Company s potential liability and expenses in this matter are not covered by insurance. An adverse outcome in this litigation could result in the Company being unable to market Cyclosporine, which could materially harm profits and cash flows, and could result in paying damages, costs, expenses and fees that could have a material adverse impact on the Company s financial performance.

The Company has denied that it has infringed any valid patent claims asserted by Apotex, has alleged affirmatively, among other things, that the patent is invalid and unenforceable and that it is not infringed by the Company s manufacture, sale or offer to sell its Cyclosporine capsules. The action remains pending.

In November 2000, Glaxo filed suit against the Company in the United States District Court for the Southern District of New York alleging infringement of two patents based on the Company s filing of an Abbreviated New Drug Application (ANDA) to market generic Bupropion Hydrochloride 100 mg and 150 mg ER (extended release) tablets. In April 2004, a Stipulation and Order was entered in the United States District Court for the Southern District of New York, terminating all pending claims and counterclaims in the patent infringement litigation that Glaxo brought against the Company in November 2000, concerning the Company s Bupropion HCl, ER 100 mg and 150 mg tablets (generic equivalents of Glaxo s Wellbutrin SR 100 mg and 150 mg tablets). Under the terms of the Stipulation and a separate Settlement Agreement, Glaxo agreed to drop any further effort to pursue its claim that the Company s Bupropion HCl, ER 100 mg and 150 mg tablets infringe Glaxo s patents. The Company received $3,000 as part of the Settlement Agreement, which was recorded as other income in the quarter ended June 30, 2004.

In July 2004, the U.S. District Court for the Eastern District of New York ruled on a pending patent infringement case that involved Itraconazole capsules. The suit, filed in April 2001 by Janssen Pharmaceutica, N.V. (Janssen), claimed that the Company s filing of an ANDA for Itraconazole capsules infringed its patent. The District Court ruling found that the Company s ANDA product did not infringe the patent, but the Court did not invalidate the patent. On August 10, 2004, Janssen filed a Notice Of Appeal to the Federal Circuit Court Of Appeals. Appellate briefs and records are currently in preparation and will be filed this year, although no date has been set for the appellate hearing.

The Company and its outside counsel believe that the Company has substantial defenses and counterclaims to the foregoing patent infringement actions, though the ultimate outcome cannot be determined.

On October 29, 2004, the Company began shipping the generic drug Citalopram Hydrobromide. Earlier in October 2004, the Company received a notice from Forest Laboratories, Inc. (Forest) and H. Lundbeck A/S (Lundbeck) that requested certain information from the Company. The notice also included a list of patents that they hold which they allege covers Citalopram Hydrobromide. To date, the Company has not been sued for patent infringement in connection with its sale of Citalopram Hydrobromide.

In addition, the Company has been named in several other patent infringement actions alleging that the Company has infringed patents by filing an application with the FDA for approval to market products before the plaintiffs patents expire. In general, plaintiffs seek judgments precluding the FDA from approving the Company s application to market a product before their respective patents expire and have asserted claims that the alleged infringements were willful, the actions are therefore exceptional and the plaintiffs should therefore be awarded the attorney s fees they have incurred in the actions.

Because predicting the ultimate outcome of these actions is not possible, no provision for any related liability has been reflected in the Company s financial statements.

Nabumetone Settlements

In August 2001, the Company was successful in defending itself in the United States District Court for the District of Massachusetts against a patent infringement claim involving Nabumetone. At the conclusion of the trial, the Company filed a motion to recover the legal fees it incurred in defending the action. The motion was stayed pending the appeal of the District Court s ruling. The Court of Appeals affirmed the District Court decision in August 2002. In May 2003, the Company and the original plaintiff reached an agreement regarding the Company s motion to recover legal fees. Under the agreement, the Company was reimbursed $3,500 for legal fees it had incurred in defending itself. The $3,500 recovery of legal fees was reflected in other selling, general and administrative expenses during the quarter ended June 30, 2003. In February 2004, the Company stipulated to an order dismissing its complaint against Glaxo for malicious prosecution of Glaxo s earlier suit against the Company, which claimed the Company s Nabumetone product infringed Glaxo s patent. In exchange for agreeing to the dismissal of its complaint, the Company received $10,000, which was included in other income in the quarter ended March 31, 2004.

Other Litigation

The Company is involved in other litigation incidental to its business activities. The ultimate disposition of such lawsuits will not materially affect the Company s financial statements.

9. Contingencies

Medicaid Rebates

The Omnibus Budget Reconciliation Act of 1990, effective January 1, 1991, as amended, requires drug companies to enter into a rebate agreement with the Centers for Medicare and Medicaid Services (formerly called the Health Care Financing Administration) of the federal government. The rebate agreement states that drug companies must pay rebates to states for drugs (prescription, non-prescription or biological products) sold to Medicaid recipients. At September 30, 2004 and December 31, 2003, $6,406 and $4,009, respectively, are included in accrued liabilities as the estimated liability for Medicaid rebates.

The Attorneys General in at least six states, including the State of Florida, sent letters to numerous pharmaceutical manufacturers during December 2003 instructing them to maintain all records relating to their reporting of pricing information under the Medicaid Drug Rebate Statute. The letters state that the document retention demand is in furtherance of an ongoing investigation of the manufacturers compliance with Medicaid drug rebate program requirements. The Company received letters from some, but not all, of the states believed to be involved, including the State of Florida. The Company believes these letters may have been motivated, at least in part, by a federal regulation published in August 2003 that, effective January 1, 2004, would have limited the document retention provisions under the federal Medicaid Drug Rebate Statute to three years unless the records are the subject of an audit or a government investigation of which the manufacturer is aware. That regulation was amended, effective January 6, 2004, to substitute a ten-year record retention requirement. The State of Florida issued subpoenas to six manufacturers requesting documents relating to their pricing and discounting practices in July 2004. The Company has not received any subpoenas, informal document requests, or any other communications from federal or state enforcement authorities that suggest an investigation of its Medicaid drug rebate reporting practices or its pricing practices is under way. The Company believes it operates in compliance with the requirements of the Medicaid Drug Rebate Statute.

State Medicaid Claims

Eon Labs Holdings, Inc. (EHI) purchased Major Pharmaceuticals, Inc. (Major), a distributor of drug products, in 1991 and sold Major in 1995. At the time of the sale, EHI established an escrow account to cover any Medicaid drug rebate liabilities incurred by Major prior to the sale.

As of September 30, 2004, the recorded liability for such claims is $817, which management believes is adequate to resolve such matters. The Company has approximately $685, as of September 30, 2004, in an escrow account to fund any such claims.

Environmental Contingencies

The Company received an inquiry from the United States Environmental Protection Agency (the EPA) in 2002 concerning the Company s relationship as a possible successor to a party that may be among a substantial number of parties liable for cleanup of the Mattiace Petrochemical Superfund site, a contaminated site currently being addressed by the EPA at a cost estimated by the EPA to be approximately $36.0 million. Based on information available at this time, the Company does not expect this matter to have a material adverse effect on its earnings or financial position.

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

The following discussion and analysis of the Company s financial condition and results of operations should be read in conjunction with the consolidated financial statements, the related notes to consolidated financial statements and Management s Discussion and Analysis of Financial Condition and Results of Operations included in the Company s annual report on Form 10-K and the unaudited interim condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

NINE MONTHS ENDED SEPTEMBER 30, 2004 COMPARED WITH NINE MONTHS ENDED SEPTEMBER 30, 2003

Net sales. Net sales increased 36.8% to $321.0 million for the nine months ended September 30, 2004 from $234.5 million in the comparable period in 2003. The majority of the sales growth was attributable to sales of Bupropion HCl, ER 100 mg and 150 mg tablets which were introduced during the first quarter of 2004. Other products introduced at the end of or subsequent to the nine months ended September 30, 2003 that also contributed to the increase in net sales include Midodrine HCl, Metolazone USP, Mirtazapine, Fosinopril, Benazepril HCl and Benazepril HCl/HCTZ.

Gross profit. Gross profit as a percentage of net sales increased to 57.3% for the nine months ended September 30, 2004 from 53.2% in the comparable period in 2003. The increase was primarily due to the benefit of a favorable product mix, principally from the introduction of Bupropion HCl, ER and increased utilization of manufacturing capacity, principally at the Company s North Carolina facility. Additionally, gross profit was impacted by a $1.8 million reduction of the Company s reserve related to promotions for which an accrual was no longer considered necessary. The Company s gross profit margins are dependent on several factors, including product sales mix, cost, volumes and competitive activity.

Selling, general and administrative. Selling, general and administrative expenses increased $11.4 million to $36.2 million for the nine months ended September 30, 2004 from $24.8 million for the comparable period in 2003. Expenses for the nine months ended September 30, 2003 were reduced by a $3.5 million recovery of legal fees related to patent infringement litigation involving Nabumetone. Excluding the recovery of legal fees, selling, general and administrative expenses increased by $7.9 million, but decreased by 0.7% as a percentage of net sales. The increase,

excluding the recovery of legal fees, is primarily attributable to increases of $2.1 million for insurance due to higher insurance premiums, principally for product liability and directors and officers coverage, $2.0 million for higher

legal costs primarily associated with patent infringement litigation, $1.5 million in increased compensation costs and $2.3 million in increases in other expenses.

Research and development. Research and development expenses increased $2.4 million to $18.3 million for the nine months ended September 30, 2004 compared to $15.9 million for the comparable period in 2003. The increase in research and development is attributed principally to an increase in the purchase of research raw materials of $1.6 million and an increase in personnel-related costs of $1.1million, offset by a decrease in expenses relating to the completion of defined milestones under third-party product development agreements of $1.0 million. The remaining $0.7 million is related to increases for various other items.

Operating income. Operating income increased $45.3 million to $129.4 million for the nine months ended September 30, 2004 from $84.1 million for the comparable period in 2003. The increase in operating income was the result of increased sales and gross profit, offset by increases in selling, general and administrative expenses and research and development costs.

Interest income. Interest income for the nine months ended September 30, 2004 was $1.6 million compared to net interest income of $0.7 million in the comparable period in 2003 due to the elimination of outstanding debt, which decreased interest expense by $0.3 million, and an increase in interest income of $0.5 million, which is the result of higher investment balances.

Other income, net. Other income for the nine months ended September 30, 2004, was $13.0 million, including a $10.0 million settlement received from Glaxo in exchange for the Company agreeing to the dismissal of its complaint against Glaxo for the malicious prosecution of its earlier suit against the Company, which claimed the Company s Nabumetone product infringed Glaxo s patent. Other income for this period also includes a $3.0 million bond received from Glaxo to settle all patent infringement litigation relating to Bupropion HCl, ER 100 mg and 150 mg tablets. Other income for the nine months ended September 30, 2003 was approximately $0.1 million.

Taxes on income. Taxes on income increased $20.8 million to $54.8 million during the nine months ended September 30, 2004 from $34.0 million for the comparable period in 2003. The increase was the result of higher pre-tax income for 2004. The effective tax rate decreased to 38.0% from 40.0% due principally to lower state and local taxes in 2004, an increase in tax-exempt interest on investments and the recognition of additional state tax credits.

Net income. Net income increased $38.2 million to $89.2 million for the nine months ended September 30, 2004 from $51.0 million in the comparable period in 2003 for the reasons described above.

THREE MONTHS ENDED SEPTEMBER 30, 2004 COMPARED WITH THREE MONTHS ENDED SEPTEMBER 30, 2003

Net sales. Net sales increased 29.1% to $109.8 million for the three months ended September 30, 2004 from $85.0 million in the comparable period in 2003. The majority of the sales growth was attributable to the introduction of Bupropion HCl, ER 100 mg and 150 mg tablets which were introduced during the first quarter of 2004. Other products introduced at the

end of or subsequent to the three months ended September 30, 2003 that contributed to the increase in net sales include Midodrine HCl, Metolazone USP, Fosinopril, Benazepril HCl and Benazepril HCl/HCTZ.

Gross profit. Gross profit as a percentage of net sales was 54.3% for the three months ended September 30, 2004 compared to 54.9% in the comparable period in 2003. The decrease in gross profit as a percentage of net sales is related to the impact of price decreases on selected products that occurred during the third quarter of 2004. The effect of price decreases was substantially offset by a favorable product mix, principally the result of the introduction of Bupropion HCL, ER and an increased utilization of manufacturing capacity, principally at our North Carolina facility. Additionally, gross profit was impacted by a $1.8 million reduction of the Company s reserve related to promotions for which an accrual was no longer considered necessary. The Company s gross profit margins are dependent on several factors, including product sales mix, cost, volumes and competitive activity.

Selling, general and administrative. Selling, general and administrative expenses increased $0.1 million to $10.8 million for the three months ended September 30, 2004 from $10.7 million for the comparable period in 2003. The increase is primarily attributable to increases of $0.3 million for insurance expense, principally due to higher insurance premiums for product liability and directors and officers coverage, $0.1 million for personnel-related expenses, $0.2 million for franchise taxes and $0.3 million in other expenses, offset by $0.8 million for lower legal costs primarily associated with Phentermine litigation.

Research and development. Research and development expenses decreased 8.8% to $6.0 million for the three months ended September 30, 2004 from $6.6 million for the comparable period in 2003. The decrease in research and development spending is due primarily to $1.8 million in lower expenses for bio-studies, payments relating to the completion of defined milestones under third-party product development agreements and lower expenses of $0.2 million in other expenses, offset by increases of $0.8 million for the purchase of research and development raw material and $0.6 million in personnel-related costs. The decrease in these expenses is related principally to the timing of such expenditures.

Operating income. Operating income increased $13.4 million to $42.7 million for the three months ended September 30, 2004 from $29.3 million for the comparable period in 2003. The increase in operating income was the result of increased sales and gross profit and decreased research and development costs, offset by increases in selling, general and administrative expenses.

Interest income. Interest income for the three months ended September 30, 2004 was $0.6 million compared to interest income of $0.3 million in the comparable period in 2003. Interest income increased by $0.3 million, the result of higher investment balances.

Taxes on income. Taxes on income increased $3.4 million to $15.3 million during the three months ended September

30, 2004 from $11.9 million for the comparable period in 2003. The increase was the result of higher pre-tax income for 2004. The effective tax rate decreased to 35.2% from 40.0%, due principally to lower state and local taxes in 2004, an increase in tax-exempt interest on investments and the recognition of additional state tax credits.

Net income. Net income increased $10.3 million to $28.1 million for the three months ended September 30, 2004 from $17.8 million in the comparable period in 2003 for the reasons described above.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were $52.1 million at September 30, 2004, compared to $43.9 million at December 31, 2003. Additionally, the Company had investments in marketable debt securities of $161.7 million at September 30, 2004, compared to $115.3 million at December 31, 2003.

The Company has a three-year $25 million credit facility which expires on December 31, 2007. Under this facility, the Company can borrow at the adjusted LIBOR rate plus 1.5%, the bank s prime rate or a fixed rate (as set by the bank). The credit facility, which is for working capital purposes, had no outstanding borrowings against it at September 30, 2004 and December 31, 2003, respectively.

Stockholders equity increased to $413.0 million at September 30, 2004 from $328.8 million at December 31, 2003. The increase in stockholders equity was comprised primarily of net earnings of $89.2 million for the nine months ended September 30, 2004, offset by net purchases of $3.4 million of treasury shares and $1.6 million (including tax benefits) from the exercise of stock options.

For the nine months ended September 30, 2004, cash increased by $8.3 million. Operations generated $75.2 million of cash, comprised of net earnings of $89.2 million, non-cash items totaling $15.8 million and an increase in working capital of $29.8 million. Working capital is defined as current assets (excluding cash and cash equivalents, investments and restricted cash) less current liabilities. The increase in working capital resulted primarily from increases in accounts receivable, inventory and prepaid expenses and other current assets of $38.7 million, $12.1 million and $15.0 million, respectively. An increase in accrued liabilities and accounts payable of $35.6 million and $0.3 million, respectively, partially offset the other working capital increases. The increases in accounts receivable and inventory are attributed to increased sales. The increase in prepaid expenses and other current assets is due to increases in prepaid insurance and income taxes. The increase in accrued liabilities is due to an increase in customer allowances. The increase in accounts payable is due to timing of payments.

Investing activities consumed $56.8 million of cash for the nine months ended September 30, 2004. Approximately $46.6 million represented net purchases of short-term investment grade debt securities and $10.2 million used for capital expenditures during the nine months ended September 30, 2004. The capital expenditures relate primarily to equipment required to support increased production volume in the Company s North Carolina facility.

Financing activities consumed $10.2 million of cash during the nine months ended September 30, 2004. The purchase of treasury shares consumed $11.2 million. Other financing activities generated $1.0 million, of which $0.9 million represents cash proceeds received from employees who exercised stock options.

The Company is involved in various product liability and patent litigation not covered by insurance. Adverse rulings in litigation related to product liability and patent infringement could result in the Company paying damages and expenses that could have a material adverse effect on the Company s financial performance. See Note 8 from Notes to Consolidated Financial Statements herein for further details.

The Company does not currently have or anticipate any short-term funding requirements outside of the ordinary course of its business, and the Company does not have or anticipate any liquidity concerns. The Company s principal future cash requirements are associated with increased working capital to support future growth, capital expenditures and legal defense costs. The Company anticipates that its operating cash flows and current cash balances, together with its available borrowings under its credit facility, will be sufficient to meet all of its cash requirements for both the short-term and foreseeable future.

Critical Accounting Policies

The Company s critical accounting policies are those policies that are important to the portrayal of its financial condition and results of operations and require management s subjective judgments. As a result, these judgments are subject to an inherent degree of uncertainty. The Company bases its judgments on its experience and various other assumptions that the Company believes to be reasonable under the circumstances. On an ongoing basis, the Company evaluates its estimates, including those related to revenues, returns, inventories, income taxes and litigation. The Company s actual results could differ from these estimates under different assumptions or conditions. The Company believes the following accounting policies to be critical:

Revenue Recognition

Sales are recognized when the products are received by the customer, which represents the point when the risks and rewards of ownership are transferred to the customer. When the Company recognizes revenue from product sales, the Company records estimates for contract pricing adjustments, rebates, discounts, expected product returns and other sales allowances. These allowances are recorded as a reduction of product sales. Contract pricing adjustments, rebates and discounts are recorded as a reduction of sales based on agreed-upon terms with the Company s customers at the time of sale.

Reserves for Contract Pricing Adjustments, Rebates and Discounts

Reserves for contract pricing adjustments and rebates represent the difference between prices wholesalers are billed by the Company for products sold and the contract prices billed by wholesalers to their customers (the Company s indirect customers) for the products. These contract pricing and rebate reserve estimates are based on agreements between the Company and its indirect customers or between the Company and the wholesalers and are recorded as a

reduction in sales at the time of sale. In determining a reserve for contract pricing adjustments and rebates, the Company estimates the amount of such pricing adjustments by product based on historical trends and changes in wholesaler or contract prices. As part of the Company s review of this estimation process, the Company obtains inventory reports from key wholesalers to determine the level of inventory in that distribution channel to compare with inventory levels used in our estimation process. The Company calculates a reserve for discounts based upon actual sales under such discount arrangements. No revisions were made to the methodology used in determining these provisions during the nine months ended September 30, 2004.

As of September 30, 2004 and December 31, 2003, accounts receivable are presented net of allowances for contract pricing adjustments, rebates and discounts of $96,617 and $94,656, respectively. When allowances against a specific customer account exceed such customer s receivable balance, the net credit balance for that customer is included in accrued liabilities. The amounts reclassified to accrued liabilities are $51,839 and $20,821 at September 30, 2004 and December 31, 2003, respectively. The increase in aggregate allowances is due to an increase in sales, principally the result of new product introductions. No revisions were made to the methodology used in determining these provisions during the nine months ended September 30, 2004.

Reserve for product returns

The Company s policy is to accept customer returns of products, which consist primarily of products whose expiration date has been exceeded, upon appropriate approval by authorized personnel of the Company. The majority of the Company s products have a two to three year expiration date. Estimates for returns, which are recorded as a reduction of sales at the time of sale, relate primarily to products expected to be returned upon expiration. The Company utilizes historical trends to estimate the amount of products expected to be returned. As of September 30, 2004 and December 31, 2003, the Company has a reserve for product returns of $29,471 and $34,992, respectively. The decrease in the reserve is primarily attributed to the issuance of credits for returns of specific products unrelated to product expiration, but instead resulting from the loss of a significant contract by a wholesaler. There were no revisions made to the methodology used in determining these provisions during the nine months ended September 30, 2004.

Pricing Adjustments, Promotions and Allowances and Medicaid Rebates

Shelf stock adjustments are provided following a reduction in the price of any of the Company s products due to changes in the competitive environment. Such adjustments are credited to the Company s customers based on their on-hand inventory quantities at the time of the reduction in price. Reserves are generally established when we reduce our prices. As of September 30, 2004 and December 31, 2003 there were no liabilities recorded for shelf stock adjustments.

The Company typically provides sales incentives to its customers at the time of a new product launch to obtain distribution and market share. Since most of these promotional arrangements do not require a minimum purchase level, they are recorded as a reduction of sales upon shipment of the customer s initial order. The Company also participates in trade show and other promotions where additional discounts may be given as an incentive for the customer to purchase products. Such discounts and incentives are recorded as a reduction of sales at the time of sale of the

related product. Since the Company allows customers to return short-dated or expired products with appropriate approval, it is in the Company s interest to ensure that its customers do not maintain excess inventory levels of our products. The Company evaluates unusually large orders to ensure that customers inventories are not in excess of their ordinary course of business inventory levels.

As of September 30, 2004 and December 31, 2003, the reserve for promotions and allowances was $19,463 and $12,381, respectively. The increase in the reserve for promotions and allowances is primarily attributed to promotions for new products launched during 2004. During the three months ended September 30, 2004, the Company recorded an adjustment to reduce its reserve accrual related to promotions by $1,760. The reduction was attributed to certain promotional programs in the final stages of their program lives and for which an accrual was no longer considered necessary.

All generic pharmaceutical manufacturers whose products are covered by the Medicaid program are required to rebate to each state a percentage of their average manufacturer s price for the products dispensed. Many states also have implemented supplemental rebate programs that obligate manufacturers to pay rebates in excess of those required under federal law. The Company estimates these rebates based on historical trends of sales for such products in each state. The reserve for Medicaid rebates at September 30, 2004 and December 31, 2003 was $7,223 and $4,892, respectively.

Reserve for pending litigation claims

In determining whether liabilities should be recorded for pending litigation claims, the Company must assess the allegations made and the likelihood that it will successfully defend itself. When the Company believes it is probable that it will not prevail in a particular matter, it will then make an estimate of the amount of liability based in part on advice of outside legal counsel. There were no liabilities recorded for pending claims as of September 30, 2004 and December 31, 2003.

Impact Of Recently Issued Accounting Standards

In January 2003, the FASB issued Fin No. 46, Consolidation of Variable Interest Entities. (as revised by Fin No. 46R). This interpretation, as revised, provides guidance with respect to the consolidation of certain entities, referred to as variable interest entities (VIEs), in which an investor is subject to a majority of the risk of loss from the VIE s activities, or is entitled to receive a majority of the VIE s residual returns. This interpretation also provides guidance with respect to the disclosure of VIEs in which an investor maintains an interest, but is not required to consolidate. The provisions of the interpretation are effective immediately for all VIEs created after January 31, 2003, or in which the Company obtains an interest after that date. For VIEs created before February 1, 2003, the provisions are effective July 1, 2003. In November 2003, the Company invested $1,150 for 50% ownership in an entity formed to provide research and development services for the Company as well as third parties. It has been determined that such investee is deemed a VIE, which has been consolidated in the Company s financial statements. The net assets and result of operations of this entity were not significant to the Company in 2004. Creditors, or beneficial interest holders, of the consolidated VIE have no recourse to the general credit of the Company.

The American Jobs Creation Act of 2004 (the Act) was signed into law in October 2004 and has several provisions for manufacturing companies, including a deduction related to qualified production activities taxable income. Under the Act, qualified production activities include the Company s manufacturing of pharmaceutical products.

The FASB is currently reviewing the impact of the qualified production activities deduction on deferred taxes and is expected to issue guidance in the fourth quarter of 2004. Until this guidance is issued, the impact on the Company cannot be determined.

Effective September 30, 2004, the Company adopted Emerging Issues Task Force No. 03-1 (EITF 03-1), The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments . EITF 03-1 is applicable to the Company s debt securities within the scope of SFAS No. 115 that are classified as available for sale. EITF 03-1 provides guidance as to when an investment is considered impaired, whether the impairment is other-than-temporary and determining the amount of the impairment loss. The guidance also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. The adoption of EITF 03-1 did not have a material impact on the Company s financial condition and results of operations. In accordance with EITF 03-1, the Company will adopt the disclosure provisions for its annual financial statements.

Off-Balance Sheet Arrangements

None.

ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The following discusses the Company s exposure to market risk related to changes in interest rates, equity prices and foreign currency exchange rates. The Company does not believe that its exposure to market risk is material.

As of September 30, 2004, the Company had cash and cash equivalents of $52.1 million. Cash equivalents are interest-bearing investment grade securities, primarily short-term, highly liquid investments with maturities at the date of purchase of less than 90 days. In addition, the Company currently owns $161.7 million in publicly traded debt securities with an average maturity of approximately 500 days, which are subject to market fluctuations.

These investments are subject to interest rate risk and will decrease in value if market interest rates increase. A hypothetical increase in the market interest rates by 10% from the rates in effect on the date of this Form 10-Q would cause the fair value of these short-term investments to decline by an immaterial amount. The Company has the ability to hold these investments until maturity, and therefore it does not expect the value of these investments to be affected to any significant degree by the effect of a sudden change in market interest rates. Declines in interest rates over time will, however, reduce the Company s interest income.

The Company currently does not have any significant foreign currency exchange rate risk.

ITEM 4 - CONTROLS AND PROCEDURES

As of the end of the period covered by this report, the Company s management performed an evaluation, under the supervision and with the participation of its Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based on that evaluation, the Company s management, including its Chief Executive Officer and Chief Financial Officer, concluded that the Company s disclosure controls and procedures were effective as of the end of the period covered by this report.

There have been no changes in the Company s internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting during the three months ended September 30, 2004.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q report contains forward-looking statements relating to future events and future performance of the Company within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including, without limitation, statements regarding the Company s expectations, beliefs, intentions or future strategies that are signified by the words expects, anticipates, intends, believes or similar language. Actual results could differ materially from those anticipated in such forward-looking statements. Some specific factors that may have a significant effect on the Company s operating results and common stock market price include:

new product introductions;

changes in the degree of competition for the Company s products;

regulatory issues, including, but not limited to, receipt of ANDA approvals from the FDA, compliance with FDA or other agency regulations or the lack or failure of either of the foregoing;

the inability to acquire sufficient supplies of raw materials;

litigation and/or threats of litigation;

changes in the Company s growth rates or the growth rate of the Company s competitors;

legislative and FDA actions with respect to the government regulation of pharmaceutical products;

public concern as to the safety of the Company s products;

changes in health care policy in the United States;

conditions in the financial markets in general or changes in general economic conditions;

the Company s inability to raise additional capital;

conditions of other generic pharmaceutical companies or the generic pharmaceutical industry generally; and

changes in stock market analyst recommendations regarding the Company s common stock, other comparable companies or the generic pharmaceutical industry generally.

All forward-looking statements included in this document are based on information available to the Company on the date hereof, and the Company assumes no obligation to update any forward-looking statements. The Company cautions investors that its business and financial performance are subject to substantial risks and uncertainties.

PART II OTHER INFORMATION

ITEM 1 LEGAL PROCEEDINGS

A lawsuit filed against the Company in 2003 alleging injury from the use of Company-manufactured Amiodarone was settled in July 2004 for nominal value.

In July 2004, the U.S. District Court for the Eastern District of New York ruled on a pending patent infringement case that involved Itraconazole capsules. The suit, filed in April 2001 by Janssen, claimed that the Company s filing of an ANDA for Itraconazole capsules infringed its patent. The District Court ruling found that the Company s ANDA product did not infringe the patent, but the Court did not invalidate the patent. On August 10, 2004, Janssen filed a Notice Of Appeal to the Federal Circuit Court Of Appeals. Appellate briefs and records are currently in preparation and will be filed this year, although no date has been set for the appellate hearing.

On October 29, 2004, the Company began shipping the generic drug Citalopram Hydrobromide. Earlier in October 2004, the Company received a notice from Forest and Lundbeck that requested certain information from the Company. The notice also included a list of patents that they hold which they allege covers Citalopram Hydrobromide. To date, the Company has not been sued for patent infringement in connection with its sale of Citalopram Hydrobromide.

ITEM 2 UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

In June 2002, the Company closed an initial public offering of its common stock. The Registration Statement on Form S-1 (File No. 333-83638) was declared effective by the Securities and Exchange Commission on May 23, 2002 and the Company commenced the offering on that date. After deducting underwriting discounts and commissions and the offering expenses, the net proceeds from the offering to the Company were approximately $139.2 million.

The Company has used proceeds from the offering as follows: (i) $66.9 million has been used to repay debt due to Hexal AG; (ii) $10.0 million has been used to repay debt incurred in connection with the acquisition of EHI; and (iii) $2.0 million has been used for general working capital purposes. The remaining $60.3 million of the proceeds to the Company from the offering are invested in cash investments and short-term investment grade debt securities. The Company anticipates using the balance of the proceeds from the offering for general corporate purposes, including funding working capital, increased research and development expenditures to expand the Company s product offerings and the potential acquisition of product lines or companies. The Company has no present understandings, commitments or agreements with respect to any acquisitions. The Company has not determined the amounts it plans to spend on any of the areas listed above or the timing of these expenditures.

ITEM 5 - OTHER INFORMATION

Audit Committee Pre-Approval of Non-Audit Services

During the quarter ended September 30, 2004 the Company s Audit Committee pre-approved one category of tax-related services for $20,000.

ITEM 6 EXHIBITS

(a) Exhibits

10.1	Amended and Restated Credit Agreement, dated as of July 30, 2004, between the Company, Eon Pharma, LLC and JPMorgan Chase Bank
31.1	Certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certifications pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification Pursuant to 18 U.S.C. Section 1350, as adopted 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.

	Eon Labs, Inc.	
November 9, 2004	By:	/s/ Bernhard Hampl, Ph.D. Bernhard Hampl, Ph.D. President, Chief Executive Officer and Director
November 9, 2004	By:	/s/ William F. Holt William F. Holt Chief Financial Officer