

EON LABS INC
Form 10-Q
May 07, 2004

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q

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

or

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**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 March 31, 2004

Eon Labs, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

13-3653818

(I.R.S. Employer Identification Number)

227-15 North Conduit Avenue

Laurelton, New York

(Address of Principal Executive Offices)

11413

(Zip Code)

(718) 276-8600

(Registrant's Telephone Number, Including Area Code)

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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 No

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 No

As of May 3, 2004, there were 44,397,712 shares of the Registrant's Common Stock, \$0.01 par value per share, outstanding.

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EXHIBIT 32.1 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

EXHIBIT 32.2 Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

PART I. FINANCIAL INFORMATION**ITEM 1. FINANCIAL STATEMENTS****Eon Labs, Inc. and Subsidiaries****Condensed Consolidated Balance Sheets**

(dollars in thousands, except per share amounts)

	March 31, 2004	December 31, 2003
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 75,057	\$ 43,852
Investments	103,737	115,281
Accounts receivable, net	48,970	35,678
Inventories	61,963	56,441
Deferred tax assets, net	55,704	56,439
Prepaid expenses and other current assets	5,813	8,096
Total current assets	351,244	315,787
Property, plant and equipment, net	50,659	50,409
Goodwill and other intangible assets, net	72,001	72,941
Other assets	2,972	2,408
Total assets	\$ 476,876	\$ 441,545
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	\$ 11,631	\$ 13,612
Accrued liabilities	95,829	89,226
Total current liabilities	107,460	102,838
Long-term liabilities		
Deferred tax liabilities, net	9,136	9,136
Deferred revenue	142	200
Other	591	591
Total liabilities	117,329	112,765

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Contingencies (Notes 8 and 9)

Stockholders equity

Common stock, par value \$.01 per share; 70,000,000 shares authorized; 44,491,162 and 44,361,912 shares issued; 44,397,412 and 44,299,812 shares outstanding at March 31, 2004 and December 31, 2003, respectively	446	444
Preferred stock, par value \$.01 per share; 5,000,000 shares authorized; none issued		
Additional paid-in capital	196,742	194,951
Retained earnings	168,091	135,774
Accumulated other comprehensive (loss) income	(47)	5
	365,232	331,174
Less: Unearned deferred stock-based compensation	(138)	(184)
Treasury stock at cost: 93,750 and 62,100 shares at March 31, 2004 and December 31, 2003, respectively	(5,547)	(2,210)
Total stockholders equity	359,547	328,780
Total liabilities and stockholders equity	\$ 476,876	\$ 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 March 31,	
	2004	2003
Net sales	\$ 104,229	\$ 70,857
Cost of sales	41,981	32,445
Gross profit	62,248	38,412
Operating expenses		
Selling, general and administrative:		
Amortization of other intangible assets	940	940
Other selling, general and administrative	12,983	8,737
Research and development	5,570	3,642
Total operating expenses	19,493	13,319
Operating income	42,755	25,093
Other income (expense), net		
Interest income	448	331
Interest expense		(284)
Other income, net	10,022	37
Total other income, net	10,470	84
Income before income taxes	53,225	25,177
Provision for income taxes	(20,908)	(10,070)
Net income	\$ 32,317	\$ 15,107
Net income per common share		
Basic	\$ 0.73	\$ 0.34
Diluted	\$ 0.71	\$ 0.33
Weighted average common shares outstanding		
Basic	44,355,387	44,113,516
Diluted	45,389,203	45,214,718

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 three months ended March 31,	
	2004	2003
Cash flows from operating activities		
Net income	\$ 32,317	\$ 15,107
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for accounts receivable allowances	4,844	14,199
Depreciation and amortization	2,550	2,146
Deferred income taxes	735	
Deferred compensation	46	112
Amortization of deferred revenue	(58)	(58)
Amortization of discount on note payable		269
Loss on foreign currency translation	(12)	
Tax benefit from exercises of stock options	3,368	887
Changes in assets and liabilities:		
Accounts receivable	(18,136)	(13,116)
Inventories	(5,522)	(9,135)
Prepaid expenses and other current assets	2,218	2,283
Other assets	(564)	(184)
Accounts payable	(1,981)	2,719
Accrued liabilities	6,629	5,859
Net cash provided by operating activities	26,434	21,088
Cash flows from investing activities		
Capital expenditures	(1,860)	(2,141)
Net sales (purchases) of short-term investments	11,478	(4,480)
Net cash provided by (used in) investing activities	9,618	(6,621)
Cash flows from financing activities		
Payment on seller note		(4,799)
Advances from related parties, net		337
Decrease in restricted cash	65	17
Proceeds from exercises of stock options	635	134
Purchase of treasury shares	(5,547)	
Net cash used in financing activities	(4,847)	(4,311)
Net increase in cash and cash equivalents	31,205	10,156
Cash and cash equivalents at beginning of period	43,852	62,323
Cash and cash equivalents at end of period	\$ 75,057	\$ 72,479

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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 March 31, 2004 and results of 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 \$99,500 and \$94,656 at March 31, 2004 and December 31, 2003, respectively.

Shelf stock adjustments are provided following a reduction in the prices of any 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 \$72,547 and \$73,086 for returns, promotional incentives and Medicaid rebates at March 31, 2004 and December 31, 2003, respectively.

Shipping and Handling Costs

The Company classifies shipping and handling costs as part of selling, general and administrative expenses. Shipping and handling costs were \$1,315 and \$1,090 for the three months ended March 31, 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 reported in other comprehensive income. The book value of such securities exceeded market value by \$59 at March 31, 2004 while the market value of such securities exceeded book value by \$7 at December 31, 2003. At March 31, 2003, the market value of such securities exceeded book value by \$49. Accordingly, net income for the three months ended March 31, 2004 and 2003 decreased by \$40 and \$14 resulting in comprehensive income of \$32,277 and \$15,093, respectively.

Other Income

Included in other income is a \$10,000 settlement received from GlaxoSmithKline (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.

2. Stockholder's Equity

Additional Paid-In Capital

Additional paid-in capital increased by \$1,791 to \$196,742 at March 31, 2004 from \$194,951 at December 31, 2003. The increase represents proceeds of \$633 from the exercise of employee stock options and \$3,368 of tax benefits associated with these exercise transactions offset by the reissuance of \$2,210 of treasury shares.

Stock Options

During the three months ended March 31, 2004, options to purchase 300,000 shares of common stock at an average exercise price of \$58.65 per share were granted. The stock options granted are exercisable for up to ten years following the date of the grant. Except for 30,000 options, which were immediately vested, the options vest and become exercisable at the rate of 20% per year.

During the three months ended March 31, 2004, 191,350 options with a weighted-average exercise price of \$3.32 were exercised and 5,600 options were terminated.

Deferred Stock-Based Compensation

The Company amortized deferred stock compensation in the amount of \$46 and \$112 for the three months ended March 31, 2004 and 2003, respectively.

Stock-Based Compensation

The Company has adopted Statement of Financial Accounting Standards (SFAS) No. 123 Accounting for Stock-Based Compensation (SFAS No. 123). 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 awards 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. The additional required disclosures are found below.

In addition, the Company provides pro forma disclosure of stock-based compensation, as measured under the fair value requirements of SFAS No. 123, Accounting for Stock-Based Compensation and as determined through the use of the Black-Scholes option pricing model. These pro forma disclosures are provided as required under SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure.

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

	March 31, 2004	March 31, 2003
Dividend yield	0%	0%
Volatility	45%	45%
Risk-free interest rate	3.0% to 4.0%	3.0% to 4.0%
Expected life	1 to 5 years	1 to 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 ended March 31, 2004 and 2003, respectively, 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	
	March 31,	
	2004	2003
Net income, as reported	\$ 32,317	\$ 15,107
Adjustment to net income for pro forma stock-based compensation expense, net of related tax effect	(922)	(126)
Pro forma net income	\$ 31,395	\$ 14,981
As reported net earnings per share:		
Basic	\$ 0.73	\$ 0.34
Diluted	\$ 0.71	\$ 0.33
Pro forma net earnings per share:		
Basic	\$ 0.71	\$ 0.34
Diluted	\$ 0.69	\$ 0.33

Stock Repurchase Program

In April 2003, the Company's Board of Directors approved the repurchase of up to 300,000 shares of the Company's common stock. In July 2003, the Company adopted a plan to repurchase up to 125,000 shares through December 31, 2003. In February 2004, the Company adopted a plan to repurchase up to 93,750 shares through March 31, 2004. In April 2004, the Company adopted a plan to repurchase up to 93,750 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 three months ended March 31, 2004, under the Company's plan, the Company repurchased 93,750 shares of its outstanding common stock at an average price of \$59.16 per share totaling \$5,547. 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 March 31,	
	2004	2003
Net income per share-basic:		
Net income	\$ 32,317	\$ 15,107
Weighted average shares outstanding-basic	44,355,387	44,113,516
Net income per share-basic	\$ 0.73	\$ 0.34
Net income per share-diluted:		
Net income	\$ 32,317	\$ 15,107
Weighted average shares outstanding-basic	44,355,387	44,113,516
Dilutive effect of stock options	1,033,816	1,101,202
Weighted average shares-diluted	45,389,203	45,214,718
Net income per share-diluted	\$ 0.71	\$ 0.33

4. Adoption of New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. 46, Consolidation of Variable Interest Entities. This interpretation provides guidance with respect to the consolidation of certain entities, referred to as variable interest entities (VIE), 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 results of operations of this entity were not significant to the Company in 2004.

5. Inventories

Inventories consist of the following:

	March 31, 2004	December 31, 2003
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Raw material	\$	24,399	\$	24,745
Work-in-process		10,128		7,529
Finished goods		27,436		24,167
	\$	61,963	\$	56,441

6. Line of Credit

On February 8, 2002, the Company entered into a three-year \$25 million credit agreement, which is collateralized by accounts receivable and inventory. 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 asset coverage, as defined. At March 31, 2004 and December 31, 2003, there were no outstanding borrowings under the line of credit.

7. Transactions Between the Company and Related Parties

The following is a summary of related party transactions:

	For the three months ended	
	March 31,	
	2004	2003
Net sales to subsidiaries of Hexal AG	\$ 564	
Purchases of products and supplies from subsidiaries of Hexal AG	607	235
Reimbursement of other expenses from Hexal AG	484	
Cyclosporine agreements with Hexal AG(1)	1,220	1,343
Fees incurred for rights of product development files of Hexal AG	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 March 31, 2004 and December 31, 2003, the Company had a payable to Hexal AG of approximately \$1,209 and \$1,102, respectively, included in accrued liabilities.

At March 31, 2004 and December 31, 2003, the Company had receivables from subsidiaries of Hexal AG of approximately \$549 and \$120, respectively, included in prepaid expenses and other current assets.

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 Food and Drug Administration (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 substantially curb their testimony 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 (the Fen-Phen MDL), certified a nationwide settlement class and approved the proposed settlement, which became final in January 2002. This settlement has reduced the number of cases in which the Company and its distributors have been named as defendants.

As of March 31, 2004, the Company had been named and served in approximately 7,057 fen-phen product liability cases. Approximately 89% of these cases have been dismissed. Since the beginning of the fen-phen litigation, only one case has gone to trial with the Company and its distributors as defendants. 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 March 31, 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.

Phentermine Litigation

The Company has been named as a defendant in several cases in which the plaintiff alleges 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 March 31, 2004 only one such claim remained 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 the three months ended March 31, 2004 and 2003 were approximately \$1,500 and \$2,400, 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 has reached an agreement in principle with its insurer regarding these insurance claims that, if completed, will defray the future cost of the Company's fen-phen defense by approximately \$1,400. Additionally, the Company has reached agreements under which the Company has agreed to fund or partially fund the defense of certain of its distributors and 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.

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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 March 31, 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.

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 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 that it is not infringed by the Company's manufacture, sale or offer to sell its Cyclosporine capsules.

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 will be recorded as income in the quarter ending June 30, 2004.

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, that the actions are therefore exceptional and that plaintiffs should therefore be awarded the attorney fees they have incurred in the actions.

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.

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 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 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 March 31, 2004 and December 31, 2003, \$5,003 and \$4,009, respectively, are included in accrued liabilities as the estimated liability for Medicaid rebates.

The Attorneys General in at least six states 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. 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 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 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. 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 March 31, 2004, the recorded liability for such claims is \$817, which management believes is adequate to resolve such matters. The Company has approximately \$684 as of March 31, 2004, in an escrow account to fund any such claims.

Environmental Contingencies

The Company received an inquiry from the United States Environmental Protection Agency (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 require significant capital expenditures or 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.

Three Months Ended March 31, 2004 Compared With Three Months Ended March 31, 2003

Net sales. Net sales increased 47.1% to \$104.2 million for the three months ended March 31, 2004 from \$70.9 million in the comparable period in 2003. The majority of the sales growth for the first quarter was due 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 subsequent to March 31, 2003 that contributed to the increase in net sales include Mirtazapine, Midodrine HCl, Nefazadone HCl, Metolazone USP, Benazepril HCl and Benazepril HCTZ.

Gross profit. Gross profit as a percentage of net sales increased to 59.7% for the three months ended March 31, 2004 compared to 54.2% 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 100 mg and 150 mg tablets. The Company's gross profit margins are dependent on several factors, including product sales mix, cost, volumes and competitive activity.

Amortization of other intangibles. Amortization of other intangibles was \$0.9 million for the three months ended March 31, 2004 and for the comparable period in 2003.

Other selling, general and administrative. Other selling, general and administrative expenses increased \$4.2 million to \$13.0 million for the three months ended March 31, 2004 from \$8.7 million for the comparable period in 2003. As a percentage of net sales, other selling, general and administrative expenses for the three months ended March 31, 2004 were consistent with the comparable period in 2003. The dollar increase is primarily attributable to increases of \$1.1 million for insurance expense due to higher insurance premiums, \$1.3 million for higher legal costs primarily associated with patent challenges, \$1.1 million in compensation costs and \$0.7 million in other expenses.

Research and development. Research and development expenses increased \$1.9 million to \$5.6 million for the three months ended March 31, 2004 from \$3.6 million in the comparable period in 2003. The increase is primarily attributable to increases in the cost for bio-studies, the purchase of materials and expenses relating to the completion of defined milestones under third-party product development agreements. These increases reflect an acceleration of the Company's product development program.

Operating income. Operating income increased \$17.7 million to \$42.8 million for the three months ended March 31, 2004 from \$25.1 million for the comparable period in 2003. The increase in operating income is the result of increased sales and gross profit, offset by increases in other selling, general and administrative expenses and research and development costs.

Interest income (expense). Net interest income for the three months ended March 31, 2004 increased \$0.4 from the comparable period in the prior year due to the elimination of outstanding debt, which decreased interest expense by \$0.3 million.

Other income, net. Other income for the three months ended March 31, 2004 included a \$10.0 million settlement received from Glaxo in exchange for agreeing to the dismissal of the Company's 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 the three months ended March 31, 2003 was less than \$0.1 million.

Taxes on income. Taxes on income increased \$10.8 million to \$20.9 million during the three months ended March 31, 2004 from \$10.1 million for the comparable period in 2003. The increase is the result of higher pre-tax income for 2004. The effective tax rate decreased to 39.3% from 40.0% due principally to lower state and local taxes in 2004.

Net income. Net income increased \$17.2 million to \$32.3 million for the three months ended March 31, 2004 from \$15.1 million for the comparable period in 2003 for the reasons described above.

Liquidity and Capital Resources

Cash and cash equivalents were \$75.1 million at March 31, 2004, as compared to \$43.9 million at December 31, 2003. Additionally, the Company had investments in marketable debt securities of \$103.7 million at March 31, 2004, as compared to \$115.3 million at December 31, 2003.

The Company has a three-year \$25 million credit facility which expires on February 8, 2005. Under this facility, the Company can borrow at LIBOR plus 1.5%, the bank's prime rate or a fixed rate. The credit facility, which is for working capital purposes, had no outstanding borrowings against it at March 31, 2004 and December 31, 2003.

Stockholders' equity increased to \$359.5 million at March 31, 2004 from \$328.8 million at December 31, 2003. The increase in stockholders' equity was primarily comprised of \$1.8 million (including tax benefits) from the exercise of stock options, net earnings of \$32.3 million for the three months ended March 31, 2004, offset by net purchases of \$3.3 million of treasury shares.

For the three months ended March 31, 2004, cash increased by \$31.2 million. Operations generated \$26.4 million of cash, comprised of net earnings of \$32.3 million, non-cash items totaling \$11.5 million, offset by an increase in working capital of \$17.4 million. The increase in working capital resulted primarily from increases in accounts receivable, inventory and other assets of \$18.1 million, \$5.5 million and \$0.6 million, respectively, and a decrease in accounts payable of \$2.0 million. A decrease in prepaid expenses and other current assets of \$2.2 million and an increase in accrued liabilities of \$6.6 million partially offset the other working capital increases. The increases in accounts receivable and inventory are attributed to increased sales. The increase in other assets is attributed to the timing of deposits on building improvements and machinery primarily to support increased production volume in the Company's North Carolina facility. The increase in accrued liabilities is due to an increase in accrued taxes. The decreases in prepaid expenses and other current assets and accounts payable are due to lower amortization of prepaid insurance and timing of payments, respectively.

Investing activities provided \$9.6 million of cash for the three months ended March 31, 2004. Approximately \$11.5 million of such amount represented net sales of short-term investment

grade debt during the three months ended March 31, 2004, offset by \$1.9 million used for capital expenditures. The capital expenditures relate primarily to machinery and equipment required to support increased production volume in the Company's North Carolina facility.

Financing activities consumed \$4.8 million of cash during the three months ended March 31, 2004. The purchase of treasury shares consumed \$5.5 million. Financing activities generated \$0.7 million, of which \$0.6 million represents cash proceeds received from employees who exercised stock options, with the remaining proceeds related to other financing activities.

The Company is involved in various product liability and patent litigation not covered by insurance. Adverse rulings in litigation related to product liability could result in the Company paying damages and expenses that could have a material adverse effect on the Company's financial performance.

An adverse outcome in patent litigation with Novartis and Apotex involving Cyclosporin capsules could result in the Company not being able to market this product, which could materially harm its profits and cash flows. Furthermore, an adverse outcome in this litigation could result in the Company paying damages, costs, expenses and fees that could have a material adverse impact on its financial performance. 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 Court of Appeals is pending.

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:

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

