

EON LABS INC  
Form 10-Q  
August 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**

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**Commission File Number 001-31333**

**For the quarterly period ended June 30, 2004**

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**Eon Labs, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**

(State or Other Jurisdiction of Incorporation)

**227-15 North Conduit Avenue  
Laurelton, New York**

(Address of Principal Executive Offices)

**13-3653818**

(I.R.S. Employer Identification Number)

**11413**

(Zip Code)

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**(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 August 4, 2004, there were 88,733,996 shares of the Registrant's Common Stock, \$0.01 par value per share, outstanding.

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**Eon Labs, Inc. and Subsidiaries**  
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**Eon Labs, Inc. and Subsidiaries**  
**Condensed Consolidated Balance Sheets**  
(dollars in thousands, except per share amounts)

	<b>June 30, 2004</b>		<b>December 31, 2003</b>	
	<b>(Unaudited)</b>			
<b>Assets</b>				
<b>Current assets</b>				
Cash and cash equivalents	\$	101,099	\$	43,852
Investments		73,111		115,281
Accounts receivable, net		59,443		35,678
Inventories		74,146		56,441
Deferred tax assets, net		55,468		56,439
Prepaid expenses and other current assets		6,136		8,096
<b>Total current assets</b>		<b>369,403</b>		<b>315,787</b>
Property, plant and equipment, net		50,994		50,409
Goodwill		46,934		46,934
Other intangible assets, net		24,127		26,007
Other assets		4,004		2,408
<b>Total assets</b>	<b>\$</b>	<b>495,462</b>	<b>\$</b>	<b>441,545</b>
<b>Liabilities and Stockholders' Equity</b>				
<b>Current liabilities</b>				
Accounts payable	\$	14,683	\$	13,612
Accrued liabilities		87,135		89,226
<b>Total current liabilities</b>		<b>101,818</b>		<b>102,838</b>
<b>Long-term liabilities</b>				
Deferred tax liabilities, net		9,136		9,136
Deferred revenue		85		200
Other		591		591
<b>Total liabilities</b>		<b>111,630</b>		<b>112,765</b>
Contingencies (Notes 8 and 9)				

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<b>Stockholders equity</b>				
Common stock, par value \$.01 per share; 100,000,000 shares authorized; 88,982,924 and 88,723,824 shares issued; 88,740,064 and 88,599,624 shares outstanding at June 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		194,413		194,507
Retained earnings		196,879		135,774
Accumulated other comprehensive (loss) income		(275)		5
		391,907		331,174
Less: Unearned deferred stock-based compensation		(92)		(184)
Treasury stock, at cost, 242,860 and 124,200 shares at June 30, 2004 and December 31, 2003, respectively		(7,983)		(2,210)
<b>Total stockholders equity</b>		383,832		328,780
<b>Total liabilities and stockholders equity</b>	\$	495,462	\$	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 June 30,				For the six months ended June 30,			
	2004		2003		2004		2003	
Net sales	\$	106,962	\$	78,681	\$	211,191	\$	149,538
Cost of sales		43,096		37,081		85,077		69,526
<b>Gross profit</b>		63,866		41,600		126,114		80,012
Operating expenses								
Selling, general and administrative								
Amortization of other intangible assets		940		940		1,880		1,880
Other selling, general and administrative		12,368		5,316		25,351		14,053
Research and development		6,689		5,680		12,259		9,322
<b>Total operating expenses</b>		19,997		11,936		39,490		25,255
<b>Operating income</b>		43,869		29,664		86,624		54,757
Other income (expense), net								
Interest income		485		333		933		664
Interest expense				(16)				(300)
Other income, net		3,024		74		13,046		111
<b>Total other income, net</b>		3,509		391		13,979		475
Income before income taxes		47,378		30,055		100,603		55,232
Provision for income taxes		(18,590)		(12,023)		(39,498)		(22,093)
<b>Net income</b>	\$	28,788	\$	18,032	\$	61,105	\$	33,139
Net income per common share								
Basic	\$	0.32	\$	0.20	\$	0.69	\$	0.38
Diluted	\$	0.32	\$	0.20	\$	0.67	\$	0.37
Weighted average common shares outstanding								
Basic		88,770,483		88,491,194		88,740,629		88,359,842
Diluted		90,828,829		90,510,290		90,803,618		90,470,086

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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 six months ended			
	June 30,			
	2004		2003	
<b>Cash flows from operating activities</b>				
Net income	\$	61,105	\$	33,139
Adjustments to reconcile net income to net cash provided by operating activities:				
Provision for accounts receivable allowances		17,288		41,847
Depreciation and amortization		5,148		4,327
Deferred income taxes		971		
Amortization of unearned deferred stock-based compensation		92		224
Amortization of deferred revenue		(115)		(115)
Amortization of discount on note payable				269
Tax benefit from exercises of stock options		4,627		2,454
Changes in assets and liabilities:				
Accounts receivable		(41,053)		(40,916)
Inventories		(17,705)		(8,483)
Prepaid expenses and other current assets		1,895		(2,184)
Other assets		(1,596)		751
Accounts payable		1,071		(510)
Accrued liabilities		(1,936)		5,040
<b>Net cash provided by operating activities</b>		29,792		35,843
<b>Cash flows from investing activities</b>				
Capital expenditures		(3,853)		(5,763)
Net sales (purchases) of short-term investments		41,772		(49,330)
<b>Net cash provided by (used in) investing activities</b>		37,919		(55,093)
<b>Cash flows from financing activities</b>				
Payment on seller note				(4,799)
Decrease in restricted cash		65		61
Proceeds from exercises of stock options		699		258
Purchase of treasury shares		(11,191)		
<b>Net cash used in financing activities</b>		(10,427)		(4,480)
Effect of exchange rate changes on cash and cash equivalents		(37)		
<b>Net increase (decrease) in cash and cash equivalents</b>		57,247		(23,730)
Cash and cash equivalents at beginning of period		43,852		62,323

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Cash and cash equivalents at end of period	\$	101,099	\$	38,593	

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 financial position as of June 30, 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 \$111,944 and \$94,656 at June 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 \$71,092 and \$73,086 for returns, promotional incentives and Medicaid rebates at June 30, 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 \$1,322 and \$1,125 for the three months ended June 30, 2004 and 2003, respectively, and \$2,637 and \$2,215 for the six months ended June 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 \$391 at June 30, 2004 and \$59 at March 31, 2004. The market value of such securities exceeded book value by \$61 and \$49 at June 30, 2003 and March 31, 2003, respectively.

The book value of such securities exceeded market value by \$391 at June 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 \$61 and \$73 at June 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 on available-for-sale securities, net of tax, and foreign currency translation losses. Total comprehensive income was \$60,840 and \$33,133 for the six month period ended June 30, 2004 and 2003, respectively, and \$28,570 and \$18,040 for the three month period ended June 30, 2004 and 2003, respectively. In accordance with SFAS 130, the accumulated unrealized gains (losses) on available-for-sale securities and losses on foreign currency

translation are shown as a separate component of stockholders' equity.

### **Other Income**

Included in other income for the three and six months ended June 30, 2004, is the receipt of a \$3,000 bond received from GlaxoSmithKline ( Glaxo ) to settle all patent infringement litigation related to the Company's Bupropion HCl, ER 100 mg and 150 mg tablets. Other income for the six months ended June 30, 2004 also includes a \$10,000 settlement received from Glaxo, recorded in the quarter ended March 31, 2004, 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**

Certain prior period amounts have been reclassified to conform to the current period presentation.

## **2. Stockholders Equity**

### **Stock Split**

On June 1, 2004, the Company 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 and per share data have been retroactively restated to reflect the impact of the stock split.

### **Additional Paid-In Capital**

Additional paid-in capital decreased by \$94 to \$194,413 at June 30, 2004 from \$194,507 at December 31, 2003. The decrease is the result of the reissuance of \$5,418 of treasury shares offset by the proceeds of \$697 from the exercise of employee stock options and \$4,627 of tax benefits associated with these exercise transactions.

### **Stock Options**

During the six months ended June 30, 2004 options to purchase 600,000 shares of Common Stock at an average exercise price of \$29.32 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 were immediately vested, the options vest and become exercisable at the rate of 20% per year.

During the six months ended June 30, 2004, 492,200 options with a weighted-average exercise price of \$1.42 were exercised and 31,200 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 June 30, 2004 and 2003, respectively, and \$92 and \$224 for the six months ended June 30, 2004 and 2003, respectively.

**Stock-Based Compensation**

The Company has adopted Statement of Financial Accounting Standards 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:

	June 30, 2004	June 30, 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 and six months ended June 30, 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 June 30,				For the six months ended June 30,			
	2004		2003		2004		2003	
Net income, as reported	\$	28,788	\$	18,032	\$	61,105	\$	33,139
Add: Compensation expenses included in net income, net of related tax effect		28		67		56		134
Less: Adjustment to net income for pro forma stock-based compensation expenses, net of related tax effect		(586)		(126)		(1,504)		(253)
Pro forma net income	\$	28,230	\$	17,973	\$	59,657	\$	33,020
As reported net earnings per share:								
Basic	\$	0.32	\$	0.20	\$	0.69	\$	0.38
Diluted	\$	0.32	\$	0.20	\$	0.67	\$	0.37



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Pro forma net earnings per share:									
Basic	\$	0.32	\$	0.20	\$	0.67	\$	0.37	
Diluted	\$	0.31	\$	0.20	\$	0.66	\$	0.37	

**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 six months ended June 30, 2004, under the Company's plan, 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 June 30,		For the six months ended June 30,	
	2004	2003	2004	2003
<b>Net income per share-basic:</b>				
Net income	\$ 28,788	\$ 18,032	\$ 61,105	\$ 33,139
Weighted average shares outstanding-basic	88,770,483	88,491,194	88,740,629	88,359,842
Net income per share-basic	\$ 0.32	\$ 0.20	\$ 0.69	\$ 0.38
<b>Net income per share-diluted:</b>				
Net income	\$ 28,788	\$ 18,032	\$ 61,105	\$ 33,139
Weighted average shares outstanding-basic	88,770,483	88,491,194	88,740,629	88,359,842
Dilutive effect of stock options	2,058,346	2,019,096	2,062,989	2,110,244
Weighted average shares-diluted	90,828,829	90,510,290	90,803,618	90,470,086
Net income per share-diluted	\$ 0.32	\$ 0.20	\$ 0.67	\$ 0.37



#### 4. Adoption of New Accounting Pronouncements

In January 2003, the FASB issued Interpretation No. (Fin ) 46 Consolidation of Variable Interest Entities (as revised by Fin 46R). This interpretation, as revised, 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 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.

In April 2004, the FASB issued Staff Position No. 129-1 (FSP 129-1), Disclosure Requirements under FASB Statement No. 129, Disclosure of Information about Capital Structure, Relating to Contingently Convertible Securities. This FSP requires the disclosure provisions of Statement No. 129 to apply to all existing and newly created contingently convertible securities and to their potentially dilutive effects on earnings per share. The Company does not have any contingently convertible securities at June 30, 2004.

#### 5. Inventories

Inventories consist of the following:

	June 30, 2004		December 31, 2003	
Raw material	\$	29,413	\$	24,745
Work-in-process		13,175		7,529
Finished goods		31,558		24,167
	\$	74,146	\$	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 June 30, 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 June 30,		For the six months ended June 30,	
	2004	2003	2004	2003
Net sales to subsidiaries of Hexal AG	\$ 484	162	\$ 1,048	162
Purchases of products and supplies from subsidiaries of Hexal AG	738	83	1,345	318
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		27	90	27
Cyclosporine agreements with Hexal AG(1)	1,137	1,788	2,357	3,131
Fees incurred under product development agreements with Hexal AG	416		716	

(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 June 30, 2004 and December 31, 2003, the Company had a payable to Hexal AG of approximately \$2,045 and \$1,102, respectively, included in accrued liabilities.

At June 30, 2004 and December 31, 2003, the Company had receivables from subsidiaries of Hexal AG of approximately \$408 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 U.S. 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 June 30, 2004, the Company had been named and served in approximately 7,207 fen-phen product liability cases. Approximately 91% 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 June 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 June 30, 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 were approximately \$3,200 and \$4,900 for the six months ended June 30, 2004 and 2003, respectively, and \$1,700 and \$2,400 for the three months ended June 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 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 phenylpropranolamine (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 June 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.

The Company was also named as a defendant in April 2004 in a lawsuit alleging injury from the use of Company-manufactured Desipramine, which has been settled in principle for a nominal amount. The Company was also named defendant in May 2004 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 principle in July 2004 for a nominal amount.

#### **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 *en banc* 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 and 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<sup>®</sup> 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 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.

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. Janssen had indicated that they will appeal the District Court decision of non-infringement.

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 June 30, 2004 and December 31, 2003, \$5,743 and \$4,009, respectively, are included in accrued liabilities as the estimated liability for Medicaid rebates.

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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. 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 June 30, 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 June 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 ( 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.

### **SIX MONTHS ENDED JUNE 30, 2004 COMPARED WITH SIX MONTHS ENDED JUNE 30, 2003**

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**Net sales.** Net sales increased 41.2% to \$211.2 million for the six months ended June 30, 2004 from \$149.5 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 June 30, 2003 that also contributed to the increase in net sales include Midodrine HCl, Metolazone USP, Mirtazapine, Benazepril HCl and Benazepril/HCTZ.

**Gross profit.** Gross profit as a percentage of net sales increased to 59.7% for the six months ended June 30, 2004 from 53.5% 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 our North Carolina facility. 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 intangible assets was \$1.9 million for the six months ended June 30, 2004 and for the comparable period in 2003.

**Other selling, general and administrative.** Other selling, general and administrative expenses increased \$11.3 million to \$25.4 million for the six months ended June 30, 2004 from \$14.1 million for the comparable period in 2003. Expenses for the six months ended June 30, 2003 were reduced by a \$3.5 million recovery of legal fees related to Nabumetone litigation. Excluding the recovery of legal fees, other selling, general and administrative expenses increased by \$7.8 million or 0.3% as a percentage of net sales. The increase, excluding the recovery of legal fees, is primarily attributable to increases of \$1.9 million for insurance expense due to higher insurance premiums for product liability and directors' and officers' coverage, \$2.8 million for higher legal costs primarily associated with patent infringement litigation, \$1.4 million in compensation costs and \$1.7 million in other expenses.

**Research and development.** Research and development expenses increased \$2.9 million to \$12.3 million for the six months ended June 30, 2004 compared to \$9.3 million for the comparable period in 2003. Increases in bio-studies expense, purchases of research and development materials, and expenses relating to the completion of defined milestones under third-party product development agreements totaled \$1.5 million. The remaining \$1.4 million of this increase is related to increases for various other items. These increases include increases in personnel costs, supplies, depreciation and other internal costs.

**Operating income.** Operating income increased \$31.9 million to \$86.6 million for the six months ended June 30, 2004 from \$54.8 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 other selling, general and administrative expenses and research and development costs.

**Interest income (expense).** Net interest income for the six months ended June 30, 2004 was \$0.9 million compared to net interest income of \$0.4 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 \$0.3 million, which is the result of higher investment balances.

**Other income, net.** Other income for the six months ended June 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 the 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 six months ended June 30, 2003 was approximately \$0.1 million.

**Taxes on income.** Taxes on income increased \$17.4 million to \$39.5 million during the six months ended June 30, 2004 from \$22.1 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 39.3% from 40.0% due principally to lower state and local taxes in 2004.

**Net income.** Net income increased \$28.0 million to \$61.1 million for the six months ended June 30, 2004 from \$33.1 million in the comparable period in 2003 for the reasons described above.

### **THREE MONTHS ENDED JUNE 30, 2004 COMPARED WITH THREE MONTHS ENDED JUNE 30, 2003**

**Net sales.** Net sales increased 35.9% to \$107.0 million for the three months ended June 30, 2004 from \$78.7 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 June 30, 2003 that contributed to the increase in net sales include Midodrine HCl, Metolazone USP, Mirtazapine, Benazepril HCl and Benazepril/HCTZ.

**Gross profit.** Gross profit as a percentage of net sales increased to 59.7% for the three months ended June 30, 2004 compared to 52.9% in the comparable period in 2003. The gross margin for the quarter ended June 30, 2004 reflected the benefit of a favorable product mix, principally from the introduction of Bupropion HCl, ER, and increased utilization of manufacturing capacity, principally at our North Carolina facility. 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 intangible assets was \$0.9 million for the three months ended June 30, 2004 and for the comparable period in 2003.

**Other selling, general and administrative.** Other selling, general and administrative expenses increased \$7.1 million to \$12.4 million for the three months ended June 30, 2004 from \$5.3 million for the comparable period in 2003. Expenses for the three months ended June 30, 2003 were reduced by a \$3.5 million recovery of legal fees related to Nabumetone litigation. Excluding the recovery of legal fees, other selling, general and administrative expenses increased by \$3.6 million or 0.4% as a percentage of net sales. The increase, excluding the recovery of legal fees, is primarily attributable to increases of \$0.8 million for insurance expense due to higher insurance premiums for product liability and directors' and officers' coverage, \$1.5 million for higher legal costs primarily associated with patent infringement litigation, \$0.3 million in compensation costs and \$1.0 million in other expenses.



**Research and development.** Research and development expenses increased 17.8% to \$6.7 million for the three months ended June 30, 2004 from \$5.7 million for the comparable period in 2003. The increase in research and development spending is due primarily to an \$0.8 million increase in expense for the purchase of research and development materials and the associated labor and overhead used in the production of research batches. The remaining \$0.2 million increase is related to increases in various other items.

**Operating income.** Operating income increased \$14.2 million to \$43.9 million for the three months ended June 30, 2004 from \$29.7 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 other selling, general and administrative expenses and research and development costs.

**Interest income (expense).** Net interest income for the three months ended June 30, 2004 was \$0.5 million compared to net interest income of \$0.3 million in the comparable period in 2003. Interest income increased by \$0.2 million, the result of higher investment balances.

**Other income, net.** Other income for the three months ended June 30, 2004, was \$3.0 million, which represents 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 three months ended June 30, 2003 was approximately \$0.1 million.

**Taxes on income.** Taxes on income increased \$6.6 million to \$18.6 million during the three months ended June 30, 2004 from \$12.0 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 39.2% from 40.0% due principally to lower state and local taxes in 2004.

**Net income.** Net income increased \$10.8 million to \$28.8 million for the three months ended June 30, 2004 from \$18.0 million in the comparable period in 2003 for the reasons described above.

## LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were \$101.1 million at June 30, 2004, as compared to \$43.9 million at December 31, 2003. Additionally, the Company had investments in marketable debt securities of \$73.1 million at June 30, 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 June 30, 2004 and December 31, 2003, respectively.

Stockholders' equity increased to \$383.8 million at June 30, 2004 from \$328.8 million at December 31, 2003. The increase in Stockholders' equity was comprised primarily of net earnings of \$61.1 million for the six months ended June 30, 2004 offset by net purchases of \$5.8 million

of treasury shares.

For the six months ended June 30, 2004, cash increased by \$57.2 million. Operations generated \$29.8 million of cash, comprised of net earnings of \$61.1 million, non-cash items totaling \$27.9 million, and an increase in working capital of \$59.3 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 other assets of \$41.1 million, \$17.7 million, and \$1.6 million, respectively, and a decrease in accrued liabilities of \$1.9 million. A decrease in prepaid expenses and other current assets of \$1.9 million and an increase in accounts payable of \$1.1 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 for future purchases. The decrease in accrued liabilities is due to a decrease in reserve for returns. The decreases in prepaid expenses and other current assets and increase in accounts payable were due to amortization of prepaid insurance and timing of payments, respectively.

Investing activities provided \$37.9 million of cash for the six months ended June 30, 2004. Approximately \$41.8 million represented net sales of short-term investment grade debt securities during the six months ended June 30, 2004 offset by \$3.9 million used for capital expenditures. The capital expenditures relate primarily to equipment required to support increased production volume in the Company's North Carolina facility.

Financing activities consumed \$10.4 million of cash during the six months ended June 30, 2004. The purchase of treasury shares consumed \$11.2 million. Other financing activities generated \$0.8 million, of which \$0.7 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 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 Cyclosporine 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 either matter 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 with respect to the Novartis matter. 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 has denied that it has infringed any valid patent claims asserted by Apotex, and has alleged affirmatively, among other things, that the patent is invalid and is not infringed by the Company's manufacture, sale or offer to sell its Cyclosporine capsules. Discovery for this

case is ongoing and is to continue through December 31, 2004. The Company expects to go to trial during the second quarter of 2005.

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 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.

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.

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.

### Impact Of Recently Issued Accounting Standards

In January 2003, the FASB issued Interpretation No. ( Fin ) 46, Consolidation of Variable Interest Entities (as revised by Fin 46R). This interpretation, as revised, 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 \$1.2 million 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.

In April 2004, the FASB issued Staff Position No. 129-1 (FSP 129-1), Disclosure Requirements under FASB Statement No. 129, Disclosure of Information about Capital Structure, Relating to Contingently Convertible Securities. This FSP requires the disclosure provisions of Statement 129 to apply to all existing and newly created contingently convertible securities and to their potentially dilutive effects on earnings per share. The Company does not have any contingently convertible securities at June 30, 2004.

### 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 June 30, 2004, the Company had cash and cash equivalents of \$101.1 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 \$73.1 million in publicly traded debt securities with an average maturity of approximately 231 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 percent 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.

#### **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;

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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**

In April 2004, a Stipulation and Order (the "Stipulation") was entered in the United States District Court for the Southern District of New York, terminating all pending claims and counterclaims in a 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<sup>®</sup> 100 mg and 150 mg tablets). Under the terms of the Stipulation and a separate settlement agreement (the "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. In April 2004, the Company received \$3.0 million as part of the Settlement Agreement. The \$3.0 million received was recorded as other income by the Company in the quarter ended June 30, 2004.

In April 2001, Janssen filed suit against the Company in the U.S. District Court for the Eastern District of New York claiming that the Company's filing of an ANDA for Itraconazole capsules infringed their patent. In July 2004, the District Court found that the Company's ANDA product did not infringe the patent, but the Court did not invalidate the patent. Janssen has indicated that they will appeal the District Court decision of non-infringement.

### **ITEM 2 CHANGES IN SECURITIES, USE OF PROCEEDS AND ISSUER PURCHASES OF EQUITY SECURITIES**

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.

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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.

The following table sets forth the repurchases of shares of the Company's common stock made during the quarter ended June 30, 2004: (1)

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plan or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs
April 1, 2004 - April 30, 2004	29,000	\$33.17	29,000	158,500
May 1, 2004 - May 31, 2004	112,760	33.88	112,760	45,740
June 1, 2004 - June 30, 2004	22,500	38.32	22,500	
Total	164,260	\$34.36	164,260	

(1) 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 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.

#### ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company's Annual Meeting of Stockholders was held on May 28, 2004, at which meeting the following actions were taken (the tabulations of the votes with respect to each action have been adjusted to reflect the 2-for-1 stock split declared May 2004 and effected on June 1, 2004 in the form of a 100% stock dividend for stockholders of record as of the close of business on May 17, 2004):

The following director was elected to serve for a term of office expiring in 2007:

	Votes For	Votes Withheld
Thomas Strüngmann, Ph.D.	71,567,236	15,177,582

As described in the Notice of Annual Meeting and Proxy Statement, abstentions and broker non-votes were not calculated in the election of directors.

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A proposal by the Board of Directors to approve an amendment to the Company's Restated Certificate of Incorporation increasing the number of authorized shares of common stock from 70 million to 100 million shares was approved by the stockholders. The stockholders cast 86,481,276 votes in favor of this proposal and 235,644 votes against. There were

27,898 abstentions. As described in the Notice of Annual Meeting and Proxy Statement, broker non-votes were not included for purposes of calculating votes on this matter.

A proposal by the Board of Directors to ratify the selection of PricewaterhouseCoopers LLP as the Company's independent auditors for the year ending December 31, 2004 was approved by the stockholders. The stockholders cast 85,692,236 votes in favor of this proposal and 1,047,284 votes against. There were 5,298 abstentions. As described in the Notice of Annual Meeting and Proxy Statement, broker non-votes were not included for purposes of calculating votes on this matter.

#### **ITEM 5 - OTHER INFORMATION**

##### **Audit Committee Pre-Approval of Non-Audit Services**

During the quarter ended June 30, 2004 the Company's Audit Committee pre-approved one category of audit-related services for \$225,000.

#### **ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K**

##### (a) Exhibits

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

##### (b) Reports on Form 8-K



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On April 22, 2004, the Company filed a Current Report on Form 8-K reporting the Press Release regarding earnings for the three months ended March 31, 2004.

**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.

August 9, 2004

By: /s/ Bernhard Hampl, Ph.D.  
Bernhard Hampl, Ph.D.  
President, Chief Executive Officer  
and Director

August 9, 2004

By: /s/ William F. Holt  
William F. Holt  
Chief Financial Officer