EON LABS INC
Form 10-Q
May 14, 2003

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**

Commission File Number 001-31333

For the quarterly period ended March 31, 2003

or

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

Eon Labs, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**13-3653818**
(State or other jurisdiction of incorporation)	(I.R.S. Employer Identification No.)
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)

Indicate by check mark whether the Registrant (1) has filed all reports required by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days: Yes ý No o

As of May 2, 2003, there were 44,199,048 shares of the Registrant s Common Stock, $0.01 par value per share, outstanding.

Table of Contents

Eon Labs, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(dollars in thousands, except per share amounts)

	March 31, 2003	December 31, 2002
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 72,479	$ 62,323
Investments	29,417	24,961
Accounts receivable, net	22,739	23,822
Inventories	51,081	41,946
Deferred tax assets, net	43,204	43,648
Prepaid expenses and other current assets	8,102	10,402
Due from related party	81	280
Total current assets	227,103	207,382
Property, plant and equipment, net	43,724	42,788
Goodwill and other intangible assets, net	75,760	76,701
Other assets	3,184	3,000
Total assets	$ 349,771	$ 329,871
Liabilities and Stockholders Equity		
Current liabilities		
Accounts payable	$ 13,693	$ 10,974
Accrued liabilities	54,772	48,785
Current portion of note payable		4,530
Total current liabilities	68,465	64,289
Long-term liabilities		
Deferred tax liabilities, net	6,998	6,998
Deferred revenue	372	430
Total liabilities	75,835	71,717

Contingencies (Notes 8 and 9)				
Stockholders equity				
Common stock, par value $.01 per share; 70,000,000 shares authorized; shares issued and outstanding 44,177,612 and 44,077,282 at March 31, 2003, and December 31, 2002, respectively		442		441
Preferred stock, par value $.01 per share; 5,000,000 shares authorized and no shares issued or outstanding at March 31, 2003 and December 31, 2002				
Additional paid-in capital		193,238		192,662
Retained earnings		80,746		65,639
Accumulated other comprehensive income		30		44
		274,456		258,786
Less: Unearned deferred stock-based compensation		(520)		(632)
Total stockholders equity		273,936		258,154
Total liabilities and stockholders equity	$	349,771	$	329,871

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,	
	2003	**2002**
Net sales	$ 70,857	$ 48,198
Cost of sales	32,445	24,985
Gross profit	38,412	23,213
Operating expenses		
Selling, general and administrative expenses:		
Amortization of other intangible assets	940	940
Other selling, general and administrative expenses	8,737	6,153
Research and development expenses	3,642	3,281
Total operating expenses	13,319	10,374
Operating income	25,093	12,839
Other income (expense), net		
Interest income	331	40
Interest expense	(284)	(2,113)
Other income, net	37	
Total other income (expense), net	84	(2,073)
Income before income taxes	25,177	10,766
Provision for income taxes	(10,070)	(4,420)
Net income	$ 15,107	$ 6,346
Net income per common share		
Basic	$ 0.34	$
Diluted	$ 0.33	$ 0.19
Weighted average common shares outstanding		

Basic		44,113,516		
Diluted		45,214,718		33,481,332

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,	
	2003	**2002**
Cash flows from operating activities		
Net income	$ 15,107	$ 6,346
Adjustments to reconcile net income to net cash provided by operating activities:		
Provision for accounts receivable allowances	14,199	18,401
Depreciation and amortization	2,146	1,902
Deferred compensation	112	290
Amortization of deferred revenue	(58)	(57)
Amortization of discount on note payable	269	519
Interest paid in-kind		1,468
Tax benefit from exercises of stock options	887	
Changes in assets and liabilities:		
Accounts receivable	(13,116)	(26,746)
Inventories	(9,135)	(1,097)
Prepaid expenses and other current assets	2,283	(2,272)
Other assets	(184)	(335)
Accounts payable	2,719	(798)
Accrued liabilities	5,859	1,768
Net cash provided by (used in) operating activities	21,088	(611)
Cash flows from investing activities		
Capital expenditures	(2,141)	(1,798)
Purchases of short-term investments	(4,480)	
Net cash used in investing activities	(6,621)	(1,798)
Cash flows from financing activities		
Payment on seller note	(4,799)	(15,201)
Proceeds from revolving line of credit		10,000
Advances from related parties, net	337	668
Decrease in restricted cash	17	67
Proceeds from exercises of stock options	134	
Net cash used in financing activities	(4,311)	(4,466)
Net increase (decrease) in cash and cash equivalents	10,156	(6,875)

Cash and cash equivalents at beginning of period			62,323			17,624
Cash and cash equivalents at end of period		$	72,479		$	10,749

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)

1. Basis of Presentation

The condensed consolidated financial statements included herein have been prepared by Eon Labs, Inc. (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 March 31, 2003 and results of operations and cash flows for the periods presented. The consolidated balances as of December 31, 2002 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, 2002. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the year.

Change of Company Ownership and Reorganization

Prior to the reorganization described below, Hexal Pharmaceuticals, Inc. (HPI), a wholly-owned United States subsidiary of Santo Holding (Deutschland) GmbH, which is under common control with Hexal AG, owned 50% of the outstanding capital stock of the Company. HPI also owned 100% of Eon Holdings, Inc. (EHI), whose principal asset was the remaining 50% ownership of the Company.

Effective May 22, 2002, in conjunction with the initial public offering of the Company s common stock, the Company was combined with HPI and EHI into a single entity through a series of reorganization mergers. EHI was merged with and into HPI and HPI was subsequently merged with and into the Company. This reorganization was accounted for as a merger of entities under common control and the accounts of the companies were combined in a manner similar to a pooling of interests effective January 1, 2000. The condensed consolidated financial statements for the three months ended March 31, 2002 reflect results on a combined basis.

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 prices billed to their customers to whom the Company has given contract prices. In determining a reserve for contract price adjustments, the Company takes into account an estimate of the percentage of product sales subect 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 $89,709 and $75,510 at March 31, 2003 and December 31, 2002, 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.

Shipping and Handling Costs

The Company classifies shipping and handling costs as part of selling, general and administrative expenses. Shipping and handling costs were $1,090 and $593 in the three months ended March 31, 2003 and 2002, respectively.

Investments

The Company invests in publicly traded debt securities which are categorized as securities available-for-sale and are carried at fair value, with unrealized gains and losses excluded from income and recorded directly to accumulated other comprehensive income. The market value of such securities exceeded book value by $49 and $73 at March 31, 2003 and December 31, 2002, respectively. Accordingly, net income is decreased by $14, resulting in comprehensive income of $15,093 for the three months ended March 31, 2003.

2. Initial Public Offering and Shareholders Equity

On June 11, 2002, the Company completed its initial public offering of common stock, which resulted in net proceeds of $139,236 and the issuance of 10,200,813 shares of common stock. Upon the consummation of the Company s initial public offering, all of the previously outstanding shares of the Company s preferred stock were converted into 30,000,000 shares of common stock and warrants were exercised resulting in the issuance of 1,680,528 shares of common stock. Immediately following the closing of the Company s initial public offering, debt of $25,178 due to Hexal AG was converted into 1,678,561 shares of common stock and debt of $66,942 due to Hexal AG was paid from the proceeds of the offering.

Stock Splits

In May 2002, the Company effected a 30-for-1 stock split of the Company s preferred stock and the Company s non-voting common stock with no change in par value. Additional paid-in capital, preferred stock, common stock, per share and shares outstanding data in the unaudited Condensed Consolidated Financial Statements and Notes to the unaudited Condensed Consolidated Financial Statements have been retroactively restated to reflect this stock split.

In May 2002, the outstanding 30,000,000 preferred shares were converted to common stock. In addition, the Company changed the number of shares of authorized preferred stock to 5,000,000, increased the number of shares of authorized voting common stock to 70,000,000 and converted shares of non-voting common stock to shares of a single class of common stock.

Deferred Stock-Based Compensation

The Company amortized deferred stock compensation in the amount of $112 and $290 for the three months ended March 31, 2003 and March 31, 2002, respectively.

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, warrants, and the conversion of preferred stock. Details of the calculations are as follows:

	For the three months ended March 31,	
	2003	**2002**
Net income per share basic:		
Net income	$ 15,107	$ 6,346
Weighted average shares basic	44,113,516	
Net income per share-basic	$ 0.34	$
Net income per share diluted:		
Net income	$ 15,107	$ 6,346
Weighted average shares outstanding basic	44,113,516	
Effect of preferred stock prior to conversion		30,000,000
Effect of warrants prior to conversion		1,680,528
Dilutive effect of stock options	1,101,202	1,800,804
Weighted average shares diluted	45,214,718	33,481,332
Net income per share diluted	$ 0.33	$ 0.19

4. Adoption of New Accounting Pronouncements

In December 2002, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 148 Accounting for Stock-Based Compensation Transition and Disclosure that amends SFAS No. 123 Accounting for Stock-Based Compensation. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 amends the disclosure requirements of Accounting Principal Board (APB) Opinion No. 28, Interim Financial Reporting and Statement No. 123 to require 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. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148, except for the disclosure requirements, had no impact on the consolidated financial statements. The additional required disclosure have been provided below.

The Company applies APB Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations in accounting for its stock-based compensation. 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, 2003	March 31, 2002
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, 2003 and March 31, 2002 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,	
	2003	2002
Net income, as reported	$ 15,107	$ 6,346
Adjustment to net income for pro forma stock-based compensation expense, net of related tax effect	(126)	(4)
Pro forma net income	$ 14,981	$ 6,342
As reported and pro forma net earnings per share:		
Basic	$ 0.34	$
Diluted	$ 0.33	$ 0.19

5. Inventories

Inventories consist of the following:

	March 31, 2003	December 31, 2002
Raw material	$ 24,733	$ 19,937
Work-in-process	10,554	9,655
Finished goods	15,794	12,354

	$	51,081	$	41,946

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, 2003, there were no borrowings outstanding 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,	
	2003	2002
Net sales to (returns from) subsidiaries of Hexal AG	$	$ (100)
Purchases of products and supplies from subsidiaries of Hexal AG	(235)	
Cyclosporine agreements with Hexal AG(a)	(1,343)	(1,059)
Interest on intercompany loans from Hexal AG		(1,468)

(a) 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.

In 2002, HPI was a party to certain research and development contracts with third parties for which Hexal AG loaned $0.7 million to HPI for the payment of its obligations. During 2002, the research and development contracts which were unrelated to the Company s business were transferred to an entity that is unrelated to the Company.

Included in accrued liabilities are amounts due to Hexal AG and subsidiaries of $2.6 million at March 31, 2003.

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 and distributors 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 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, 2003, the Company had been named and served in approximately 6,400 fen-phen product liability cases. More than 96% of these cases have been dismissed, and fewer than 190 remained open. Since the beginning of the fen-phen litigation, only one case has gone to trial with the Company and its distributors as defendants. In that case, the Company and all the phentermine defendants, including other phentermine manufacturers and distributors, were 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, 2003, 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, 2003 only two such claims remained pending.

Both cases are currently pending in a consolidated federal fen-phen multidistrict litigation pending in the United States District Court for the Eastern District of Pennsylvania.

Additionally, the Company has been named as a defendant in one state court case alleging injury from the use of Company phentermine in combination with phenylpropanolamine (PPA) made by another company. The Company has filed an unopposed motion to dismiss this claim and that motion is pending.

Because discovery has not been completed in these pending cases, predicting the ultimate outcome of these actions is not possible, and no provision for any liability has been reflected in the Company s financial statements. The Company believes it has substantial defenses to these claims.

Gross sales of phentermine by the Company for the three months ended March 31, 2003 and March 31, 2002 were $5,666 and $7,464, 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 the fen-phen, phentermine-only and phentermine-PPA product liability lawsuits. Additionally, the Company has reached agreements under which the Company will fund or partially fund the defense of certain of its distributors, and to indemnify them provided certain conditions are met. Further, the Company has reached favorable defense/indemnity agreements with several retailers, and is negotiating the resolution of several additional claims with other retailers. 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 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, respectively.

To date, the Company has been named in six lawsuits alleging injury or wrongful death from the use of Company-manufactured pharmaceuticals containing PPA. As of March 31, 2003, all but two PPA cases against the Company had been dismissed or discontinued. Discovery in these two lawsuits has yet to begin. The first lawsuit is pending in state court in New York. The second lawsuit was filed in the United States District Court for the District of Maryland and served upon the Company in January 2003. It is likely to be transferred to the the consolidated federal phenylpropanolamine multidistrict litigation (PPA MDL) pending in the United States District Court for the Western District of Washington. Because these two lawsuits were only recently filed, and discovery in them has yet to begin, predicting the ultimate outcome of these actions is not possible, no provision for any liability has been reflected in the Company s financial statements.

Patent Infringement Litigation

On August 30, 2000, Novartis Pharmaceuticals Corporation 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. An adverse outcome in patent litigation with Novartis involving cyclosporine capsules could result in the Company being unable to market this product which would materially harm its profits and cash flows and could result in the Company paying damages, cost, expenses, and fees that could have a material adverse impact on its financial performance. The Company s potential liability and expenses in this matter are not covered by insurance. 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. Novartis has appealed the judgment. The ultimate outcome of this lawsuit cannot be determined at this time.

In January 2001, Apotex, Inc. 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 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 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 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 the product before their patent expires and have asserted claims that the alleged infringement was willful, that the action is therefore exceptional and that plaintiffs should therefore be awarded the attorney fees they have incurred in the action.

The Company and its outside counsel believe that the Company has substantial defenses and counterclaims to these above 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 liability has been reflected in the Company s financial statements.

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

Rebates

The Omnibus Budget Reconciliation Act of 1990, effective January 1, 1991, requires drug companies to enter into a rebate agreement with 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, 2003 and December 31, 2002, $4,260

and $4,055, respectively, are included in accrued liabilities as the estimated liability for Medicaid rebates.

State Medicaid Claims

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

As of March 31, 2003, the recorded liability for such claims is $927, which management believes is adequate to resolve such matters. The Company has approximately $791 as of March 31, 2003 in an escrow account to resolve such claims.

FDA Regulations

In January 2003, the Company received Inspectional Observations - Form FDA 483 (the FDA 483) at its Laurelton facility following the mislabeling of one lot of product that was distributed. The mislabeled lot was recalled. The Company provided a written response to the FDA 483 discussing the implementation of corrective actions and revisions to procedures that the Company believes addresses the concerns and issues raised by the FDA 483. In February 2003, the FDA issued a Warning Letter and requested that the Company clarify and supplement its responses to the FDA 483. The Company has provided its supplemental responses to the FDA. Based on follow-up discussions with the FDA, the Company has been advised that a Current Good Manufacturing Practices or GMP inspection will be conducted by the FDA at the Laurelton facility beginning in May 2003.

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/A and the unaudited interim condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

THREE MONTHS ENDED MARCH 31, 2003 COMPARED WITH THREE MONTHS ENDED MARCH 31, 2002

Net sales. Net sales increased 47.0% to $70.9 million for the three months ended March 31, 2003 from $48.2 million in the comparable period in 2002. The majority of the net sales increase was attributable to products introduced subsequent to March 31, 2002. These products include Lisinopril, USP, Lisinopril/HCTZ, Tizanidine HCl, Tramadol HCL and Nizatidine, USP. In addition, the Company also introduced a Dextroamphetamine and Amphetamine Mix Salt Product. An increase in unit volume of several existing products also contributed to higher sales for the three months ended March 31, 2003.

Gross profit. Gross profit as a percentage of net sales increased to 54.2% for the three months ended March 31, 2003 compared to 48.2% in the comparable period in 2002. The increase was primarily due to increased utilization of manufacturing capacity, including a significant increase in production at the Company s North Carolina facility. Additionally, in 2002 there was a $1.6 million write down of a raw material that will not be utilized in production. The Company s gross profit margins are dependent on several factors, including product sales mix, cost, volumes and competitive activity.

Amortization of other intangible assets. Amortization of other intangible assets was $0.9 million for the three months ended March 31, 2003 and for the comparable period in 2002.

Other selling, general and administrative. Other selling, general and administrative expenses increased $2.6 million to $8.7 million for the three months ended March 31, 2003 compared to $6.2 million in the comparable period in 2002. As a percentage of net sales, other selling, general and administrative expenses decreased to 12.3% for the three months ended March 31, 2003 from 12.8% in the comparable period in 2002. The increase in other selling, general and administrative expenses was principally due to higher insurance, legal and distribution expenses. Insurance expense increased by $1.1 million, primarily the result of higher product liability and director and officers insurance premiums. Legal expenses increased $0.7 million, of which $0.4 million is associated with patent litigation activities, with much of the remaining balance being for additional compliance and reporting requirements of a publicly-traded company. Higher sales volume increased distribution expense by $0.5 million.

Research and development. Research and development expenses increased $0.4 million to $3.6 million for the three months ended March 31, 2003 compared to $3.3 million for the comparable period in 2002. The increase was attributable to an increase in generic drug development of $0.9 million offset by a decrease of $0.5 million related to certain basic research contracts unrelated to the Company s business that were transferred in March 2002 to an unrelated entity. The increase in generic drug development costs was primarily attributed to increases in costs related to personnel, bio-studies, materials and supplies.

Operating income. Operating income increased $12.3 million to $25.1 million for the three months ended March 31, 2003 from $12.8 million for the comparable period in 2002. 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 March 31, 2003 was $0.05 million compared to net interest expense of $2.1 million in the comparable period in 2002. A decrease in outstanding debt, including the elimination of $92.1 million of intercompany debt, reduced interest expense by $1.8 million. Interest income increased by $0.3 million, the result of higher investment balances.

Taxes on income. Taxes on income increased $5.7 million to $10.1 million during the three months ended March 31, 2003 from $4.4 million in the comparable period in 2002. The increase was the result of higher pre-tax income for 2003. The effective tax rate decreased to 40.0% from 41.1% due principally to lower state and local taxes in 2003.

Net income. Net income increased $8.8 million to $15.1 million for the three months ended March 31, 2003 from $6.3 million in the comparable period in 2002 for the reasons described above.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were $72.5 million at March 31, 2003 compared to $62.3 million at December 31, 2002. Additionally, at March 31, 2003 the Company had investments in marketable debt securities of $29.4 million and no outstanding debt.

The Company also 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, 2003.

Stockholders equity increased to $273.9 million at March 31, 2003 from $258.2 million at December 31, 2002. Stockholders equity increased by $0.6 million (including tax benefits) from the exercise of employee stock options, net earnings of $15.1 million for the three months ended March 31, 2003 and $0.1 million for the amortization of deferred stock-based compensation costs.

During the three months ended March 31, 2003, the Company generated net cash of $10.2 million. Operations generated $21.1 million of cash, comprised of net earnings of $15.1 million and non-cash items totaling $17.6 million offset by an increase in working capital of $11.6 million. The increase in working capital resulted from increases in accounts receivable, inventory and other assets of $13.1 million, $9.1 million and $0.2 million, respectively. A decrease in prepaid expenses and other current assets of $2.3 million and increases in accounts payable and accrued liabilities of $8.6 million partially offset the other working capital increases. The increases in accounts receivable, inventory, accounts payable and accrued liabilities are associated with higher sales and production levels. Prepaid expenses were lower due to amortization of prepaid insurance during the period.

Investing activities consumed $6.6 million of cash during this period. Approximately $4.5 million was used to purchase short-term investment grade debt instruments with the balance of $2.1 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 $4.3 million of cash during the three months ended March 31, 2003, with $4.8 million used to pay the remaining balance of the EHI acquisition note. Additional sources of cash during this period included $0.3 million related to an increase in advances from an affiliate and $0.1 million of proceeds from the exercise of stock options.

The Company is involved in various litigation matters in which the potential liabilities and/or related expenses are not covered by insurance. In addition, an adverse outcome in patent litigation with Novartis and Apotex involving cyclosporine capsules could result in the Company being unable to market this product which would materially harm its profits and cash flows and could result in the Company paying damages, cost, expenses, and fees that could have a material adverse impact on its financial performance. In December 2002, the United States District for the District of Delaware granted the Company s motion in the Novartis case for summary judgment of non-infringement of the patent. Novartis has appealed the judgment.

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, together with its available borrowings under its credit facility and current cash balances will be sufficient to meet all of its working capital and capital expenditure 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. Sales are shown net of discounts, rebates, contract pricing adjustments and returns, which are estimated based on the Company s experience. 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 prices billed to their customers to whom the Company has given contract prices. 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 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.

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 December 2002, the FASB issued SFAS No. 148 Accounting for Stock-Based Compensation Transition and Disclosure that amends FASB Statement No. 123 Accounting for Stock-Based Compensation. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 amends the disclosure requirements of APB Opinion No. 28, Interim Financial Reporting and Statement No. 123 to require 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. SFAS No. 148 is effective for fiscal years ending after December 15, 2002. The adoption of SFAS No. 148, except for the disclosure requirements, had no impact on the consolidated financial statements. The additional required disclosure is included as part of note 4 in the notes to the consolidated financial statements on Form 10-Q.

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 March 31, 2003, the Company had cash and cash equivalents of $72.5 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. These investments are subject to interest rate risk and will decrease in value if market interest rates increase. A hypothetical increase or decrease 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 insignificant 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 owns $29.4 million in publicly traded debt securities which are subject to market fluctuations.

The Company currently does not have any international operations or any significant assets or liabilities denominated in foreign currencies, and currently does not enter into forward exchange contracts or other financial instruments with respect to foreign currency. Accordingly, the Company currently does not have any significant foreign currency exchange rate risk.

ITEM 4. CONTROLS AND PROCEDURES

As of March 31, 2003, an evaluation was performed under the supervision and with the participation of the Company s management, including the Chief Executive Officer and the Chief Financial Officer, of the effectiveness of the design and operation of the Company s disclosure controls and procedures. Based on that evaluation, the Company s management, including the Chief Executive Officer and the Chief Financial Officer, concluded that the Company s disclosure controls and procedures were effective as of March 31, 2003. There have been no significant changes in the Company s internal controls or in other factors that could significantly affect the internal controls subsequent to March 31, 2003.

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 Company s competitors growth rates;

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.

18

PART II. OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

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

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

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

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

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Eon Labs, Inc

May 14, 2003	By	/s/ Bernhard Hampl, Ph.D. Bernhard Hampl, Ph.D. President, Chief Executive Officer and Director
May 14, 2003	By	/s/ William F. Holt William F. Holt Chief Financial Officer

Certification

I, Bernhard Hampl, Ph.D., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eon Labs, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ Bernhard Hampl, Ph.D.
Bernhard Hampl, Ph.D.
Chief Executive Officer

Certification

I, William F. Holt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Eon Labs, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent function):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: May 14, 2003

/s/ William F. Holt
William F. Holt

Chief Financial Officer