

EON LABS INC  
Form 10-Q  
November 14, 2002

**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**

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Commission File Number 011-31333

For the quarterly period ended September 30, 2002

or

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

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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**

**13-3653818**  
(I.R.S. Employer Identification Number)

**11413**

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(Address of Principal Executive Offices)

(Zip Code)

**(718) 276-8600**

(Registrant's Telephone Number, Including Area Code)

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

As of November 14, 2002, there were 43,559,902 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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EXHIBIT 99.2	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	

**Eon Labs, Inc. and Subsidiaries****Condensed Consolidated Balance Sheets**

(dollars in thousands, except per share amounts)

	December 31, 2001	September 30, 2002 (Unaudited)
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 17,624	\$ 40,945
Restricted cash in escrow	877	806
Investments		19,328
Accounts receivable, net of allowances of \$6,882 and \$53,649 in 2001 and 2002, respectively	27,290	53,403
Inventories	31,192	39,903
Deferred tax assets, net	19,566	19,566
Prepaid expenses and other current assets	4,478	18,815
Due from related party	200	76
<b>Total current assets</b>	<b>101,227</b>	<b>192,842</b>
Property, plant and equipment, net	38,496	41,644
Goodwill and other intangible assets, net	78,805	77,814
Other assets	874	2,380
<b>Total assets</b>	<b>\$ 219,402</b>	<b>\$ 314,680</b>
<b>Liabilities and Stockholders Equity</b>		
<b>Current liabilities</b>		
Accounts payable	\$ 10,430	\$ 12,272
Accrued expenses and other liabilities	37,301	47,986
Current portion of note payable	24,400	4,444
<b>Total current liabilities</b>	<b>72,131</b>	<b>64,702</b>
<b>Long-term liabilities</b>		
Long-term portion of note payable	2,353	
Deferred tax liabilities, net	7,153	7,153
Deferred revenue	660	489
Loans and advances from Hexal AG	90,114	
<b>Total liabilities</b>	<b>172,411</b>	<b>72,344</b>

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Contingencies (Note 8)

**Stockholders equity**

Class A voting common stock, par value \$.01 per share; 60,000,000 shares authorized, no shares issued or outstanding at December 31, 2001, and no shares authorized or outstanding at September 30, 2002			
Common stock, par value \$.01 per share; no shares authorized or outstanding at December 31, 2001, and 70,000,000 authorized and 43,559,902 outstanding at September 30, 2002			436
Class B convertible, non-voting common stock, par value \$.01 per share; 3,000,000 shares authorized and no shares issued or outstanding at December 31, 2001; and no shares authorized or outstanding at September 30, 2002			
Preferred stock, par value \$.01 per share, Series A convertible; 35,000,000 shares authorized, 30,000,000 issued and outstanding at December 31, 2001 and no shares authorized or outstanding at September 30, 2002		300	
Preferred stock, par value \$.01 per share; no shares authorized and no shares issued or outstanding at December 31, 2001, and 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2002			
Additional paid-in capital	26,101		190,380
Retained earnings	22,376		52,409
Accumulated other comprehensive income			31
	48,777		243,256
Less: Unearned deferred stock-based compensation	(1,786)		(920)
<b>Total stockholders equity</b>	46,991		242,336
<b>Total liabilities and stockholders equity</b>	\$ 219,402	\$	314,680

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

## Eon Labs, Inc. and Subsidiaries

## Condensed Consolidated Statements of Income

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

	For the three months ended September 30,				For the nine months ended September 30,			
	2001		2002		2001		2002	
Net sales	\$	42,545	\$	75,351	\$	124,227	\$	175,549
Cost of sales		18,890		35,081		53,657		83,763
<b>Gross profit</b>		23,655		40,270		70,570		91,786
Operating expenses								
Selling, general and administrative expenses:								
Amortization of goodwill and other intangibles		1,780		940		5,340		2,820
Deferred stock appreciation rights compensation		3,279				9,837		
Other selling, general and administrative expenses		6,475		11,399		19,035		24,627
Research and development expenses		3,240		3,974		8,351		10,240
<b>Total operating expenses</b>		14,774		16,313		42,563		37,687
<b>Operating income</b>		8,881		23,957		28,007		54,099
Other income (expense), net								
Interest income		107		353		347		519
Interest expense		(2,341)		(310)		(7,027)		(3,754)
Other income, net				39		6		50
<b>Total other income (expense), net</b>		(2,234)		82		(6,674)		(3,185)
Income before income taxes		6,647		24,039		21,333		50,914
Provision for income taxes		(3,004)		(9,856)		(9,642)		(20,881)
<b>Net income</b>	\$	3,643	\$	14,183	\$	11,691	\$	30,033
Net income per common share								
Basic	\$		\$	0.33	\$		\$	1.44
Diluted	\$	0.11	\$	0.31	\$	0.37	\$	0.77

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Weighted average common shares outstanding						
Basic			43,559,902			20,845,282
Diluted		31,680,528	45,387,515		31,680,528	39,134,205

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

## Eon Labs, Inc. and Subsidiaries

## Condensed Consolidated Statements of Cash Flows

(dollars in thousands) (unaudited)

	For the nine months ended September 30,			
	2001		2002	
<b>Cash flows from operating activities</b>				
Net income	\$	11,691	\$	30,033
Adjustments to reconcile net income to net cash provided by operating activities:				
Provision for accounts receivable allowances		(3,574)		46,767
Depreciation and amortization		7,767		5,692
Deferred compensation		9,837		866
Amortization of deferred revenue		(422)		(171)
Amortization of discount on note payable		2,009		1,063
Interest paid in-kind		4,899		2,463
Changes in assets and liabilities:				
Accounts receivable		(1,797)		(72,880)
Inventories		(6,068)		(8,711)
Prepaid expenses and other current assets		(3,420)		(14,337)
Other assets		(559)		(1,506)
Accounts payable		2,331		1,842
Accrued expenses and other liabilities		414		9,540
Deferred revenue		325		
<b>Net cash provided by operating activities</b>		23,433		661
<b>Cash flows from investing activities</b>				
Capital expenditures		(2,656)		(6,020)
Purchases of short-term investments				(19,297)
<b>Net cash used in investing activities</b>		(2,656)		(25,317)
<b>Cash flows from financing activities</b>				
Decrease in loans and advances to Hexal AG		(8,335)		(66,942)
Payment on seller note				(25,201)
Proceeds from initial public offering of common stock				142,303
Costs of initial public offering of common stock				(3,066)
Advances from related parties, net		158		812
Decrease in restricted cash		701		71
<b>Net cash (used in) provided by financing activities</b>		(7,476)		47,977



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<b>Net increase in cash and cash equivalents</b>		13,301		23,321
Cash and cash equivalents at beginning of period		6,378		17,624
Cash and cash equivalents at end of period	\$	19,679	\$	40,945
Non-cash investing activities:				
Unrealized gain on investments	\$		\$	31
Non-cash financing activities:				
Conversion of preferred stock	\$		\$	300
Exercise of warrants	\$		\$	17
Issuance of common stock to repay loans and advances to Hexal AG	\$		\$	25,178

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 September 30, 2002 and results of operations and cash flows for the periods presented. The consolidated balances as of December 31, 2001 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, 2001. 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 ( Santo or the Parent ), which is under common control with Hexal AG, owned 50% of the outstanding capital stock of the Company. The remaining 50% was owned by Eon Holdings, Inc. ( EHI ), whose principal asset was its 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 and nine months ended September 30, 2001 and 2002 reflect results on a combined basis.

***Shipping and Handling Costs***

The Company classifies shipping and handling costs as part of selling, general and administrative expenses. Shipping and handling costs were \$0.5 million and \$1.0 million in the three months ended September 30, 2001 and 2002, respectively, and \$1.3 million and \$2.2 million for the nine months ended September 30, 2001 and 2002, respectively.

***Investments***

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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 stockholders' equity. The market value of such securities exceeded book value by \$0.03 million at September 30, 2002. Accordingly, recording comprehensive income items (unrealized gains on marketable securities) increases net income by \$0.03 million for the nine months ended September 30, 2002.

**2. Initial Public Offering and Shareholders' Equity**



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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 with 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 of \$288 and \$866 during the three and nine months ended September 30, 2002, respectively.

### **3. Earnings Per Share**

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Basic net income per share is computed by dividing net income by the weighted average number of common shares outstanding for the period. There were no common shares outstanding for the three and nine months ended September 30, 2001. For the three and nine months ended September 30, 2002, diluted earnings per share reflect the conversion of preferred stock and the potential dilution of warrants. Diluted earnings per share for the three and nine months ended September 30, 2002 include 30,000,000 shares of preferred stock assumed converted to common and the dilutive effect of warrants of 1,680,528 shares. Basic weighted average shares outstanding for the three and nine months ended September 30,

2002 reflect the impact of common shares issued resulting from the conversion of 30,000,000 shares of preferred stock converted to common stock, the exercise by warrant holders of 1,680,528 shares, debt of \$25,178 converted to 1,678,561 shares and the issuance of 10,200,813 shares in connection with the Company's initial public offering. The issuance of such shares resulted in basic weighted average shares outstanding of 43,559,902 and 20,845,282 for the three and nine months ended September 30, 2002. The weighted average common shares outstanding used for calculating basic earnings per share are significantly higher for the three months ended September 30, 2002 than for the nine month period because there were no common shares outstanding until May 23, 2002. Weighted average shares outstanding on a diluted basis for the 2002 periods reflect the shares issued as noted above, assuming that the preferred stock that was converted to common was outstanding for the full nine-month period and the diluted effect of stock options of 1,827,613 and 1,811,164 for the three and nine-month periods ended September 30, 2002, respectively, which resulted in weighted average shares outstanding on a diluted basis of 45,387,515 and 39,134,205, respectively.

**4. Adoption of New Accounting Pronouncements**





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In July 2001, the Financial Accounting Standards Board issued SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets which have finite lives must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. The Company has completed its impairment assessment and determined that there is no impairment of goodwill or identifiable intangibles upon initial adoption of SFAS No. 142. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. The value of the Company's existing products is an intangible asset with a finite life that is being amortized over 10 years. The Company's goodwill and workforce intangibles which were being amortized over 15 and 5 year lives, respectively, have not been amortized during the nine-month period ended September 30, 2002. Had this pronouncement been retroactively applied, net income would have increased approximately \$835 and \$2,505, respectively, and diluted earnings per share would have increased \$0.03 per share and \$0.08 per share, respectively, in the three and nine months ended September 30, 2001. In 2002, the Company transferred the net book value of its workforce intangible of \$1,136 to goodwill, resulting in goodwill of \$47,107. The recorded amount of the existing product intangible of \$37,600, before accumulated amortization of \$6,893 as of September 30, 2002, will be amortized through 2010 with annual charges of \$3,760.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, that replaces SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of. SFAS No. 144 requires that long-lived assets be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. SFAS No. 144 is effective for fiscal years beginning after

December 15, 2001. The adoption of SFAS No. 144 did not have a material impact on the measurement of its long-lived assets.

In April 2002, the Financial Accounting Standards Board issued SFAS No. 145 Rescission of FAS Nos. 4, 44, and 64, Amendment of SFAS 13, and Technical Corrections as of April 2002 . This Statement amends SFAS No. 13, *Accounting for Leases*, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions as well as other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. SFAS No. 145 is effective for fiscal years beginning after December 31, 2002. The Company does not anticipate that the adoption of SFAS No. 145 will have a material impact on the consolidated financial statements.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146 Accounting for Costs Associated with Exit or Disposal Activities . This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ( EITF ) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 is effective for fiscal years beginning after December 31, 2002. The Company does not anticipate that the adoption of SFAS No. 146 will have a material impact on the consolidated financial statements.

**5. Inventories**

Inventories consist of the following:

	December 31, 2001		September 30, 2002	
Raw material	\$	16,909	\$	19,008
Work-in-process		6,026		9,576
Finished goods		8,257		11,319
	\$	31,192	\$	39,903

**6. Line of Credit**



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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 September 30, 2002, there were no borrowings outstanding under the line of credit.

**7. Related Party Transactions**





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The amounts due to Hexal AG increased from \$90,114 at December 31, 2001 to \$92,120 at March 31, 2002 due to interest charges of \$1,468 and advances of \$538. The balance was extinguished in May 2002 by a cash payment of \$66,942 with the balance of \$25,178 settled through the issuance of 1,678,561 shares of common stock. Additional interest charges were \$995 for the three months ended June 30, 2002. There were no interest charges for the three months ended September 30, 2002.

During the three and nine months ended September 30, 2002, the Company incurred royalty expense of \$491 and \$2,296 to Hexal AG. Subsidiaries of Hexal AG returned \$0.1 million of products to the Company in the nine months ended September 30, 2002.

The Company reimbursed Hexal AG \$0.1 million for expenditures that Hexal incurred on behalf of the Company during the three months ended September 30, 2002.

Included in accrued expenses are amounts due to Hexal AG of \$206 at September 30, 2002.

### 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 defendants manufacturers and distributors of phentermine and two other anti-obesity drugs, fenfluramine and dexfenfluramine. Fenfluramine and phentermine were prescribed in combination in an off-label use commonly called fen-phen, while dexfenfluramine was generally prescribed alone. The plaintiffs in these cases (the fen-phen cases) claim that taking these drugs results in instances of valvular heart disease, primary pulmonary hypertension, and other injuries. Plaintiffs seek payment of unspecified damages and medical monitoring of people who took either the fen-phen combination or fenfluramine or dexfenfluramine alone. In September 1997, the manufacturers 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.

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.

Additionally, in August 2000, the United States District Court for the Eastern District of Pennsylvania certified a nationwide settlement class and approved a proposed settlement put forth by Wyeth (formerly American Home Products), the principal defendant in the fen-phen litigation. The settlement excludes claims for certain serious medical conditions. The Court's order became final in January 2002. Although claims against Eon were not part of this settlement, the Company believes this settlement will result in additional cases being dismissed as to the Company, its customers and other phentermine defendants.

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 October 30, 2002, over 96% of the fen-phen cases filed against the Company had been dismissed. All of the dismissals in fen-phen cases were accomplished without the Company paying any judgments or settlements.

#### *Phentermine Litigation*

Additionally, the Company has been named as a defendant in several cases alleging injury from the use of phentermine alone, and in one case alleging injury from the use of the Company's phentermine in combination with phenylpropanolamine (PPA) made by another company. One of these cases was recently resolved, and discovery and trial preparation in the balance of these cases is ongoing. The Company believes it has substantial defenses to these claims, though their ultimate outcome cannot be determined.

#### *Defense Costs Related To Fen-Phen And Phentermine Litigation*

The Company has exhausted its insurance coverage for all fen-phen claims, and for non-combination phentermine claims that allege ingestion prior to June 1998. Because predicting the ultimate outcome of those lawsuits is not possible, no provision for any liability has been reflected in the Company's financial statements. Defense costs are being expensed as incurred. Such costs for the three months and nine months ended September 30, 2002, were \$1.4 million and \$3.1 million, respectively.

Gross sales of phentermine by the Company for the three months and for the nine months ended September 30, 2002, were \$6.2 million and \$25.9 million, respectively.

#### *Other Product Liability Litigation*

In addition to the litigation described above, the Company has been named as a defendant in several other product liability lawsuits. Three of the lawsuits allege injury or wrongful death from the use of Company-manufactured pharmaceuticals containing phenylpropanolamine (PPA). The Company manufactured two low-volume prescription products containing PPA that were discontinued in 1999 and 2000, respectively. The single wrongful death claim, a



federal case, was dismissed without prejudice in the Company's favor in November 2001 because plaintiffs failed to prosecute the claim, and plaintiffs have indicated that they might seek to reinstate the case. A second case was served on the Company in January 2002 and was subsequently dismissed without prejudice. The third case was served on the Company in June 2000. All federal cases involving PPA claims are subject to transfer to the nationwide, multi-district litigation now pending in the United States District Court for the Western District of Washington.

Finally, the Company was a defendant in a lawsuit alleging injury from use of leuprolide acetate, a drug that is distributed by the Company. The plaintiff alleged various injuries from taking the drug. The Company was defended in this action by the supplier's insurance company, which recently settled the case at no cost to the Company.

#### *Indemnity Related to Fen-phen and Phentermine Litigation*

The Company's product liability coverage was obtained on a claims made basis and covers liability for judgments and settlements and legal defense costs. On or about April 2000, the Company had exhausted all its available product liability coverage for all fen-phen claims and for non-combination phentermine claims that allege ingestion prior to June 1998 that aggregated approximately \$48 million. Beginning in May 2000, the Company began to provide for legal defense costs based on services rendered on behalf of the Company and its customers. Coinciding with the exhaustion of its insurance coverage, the Company entered into negotiations with several of its customers to reduce legal costs by streamlining their legal defense structure and or by increasing their contributions to defense costs. The Company has obtained written agreements with these customers.

#### *Patent Infringement Litigation*

In 2000, Novartis Pharmaceuticals Corporation filed an action in the United States District Court for the District of Delaware alleging that by manufacturing, using, selling and offering to sell cyclosporine capsules the Company is infringing on a Novartis patent. Novartis 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 Novartis should therefore be awarded the attorney fees it has incurred in the action. The Company has denied that it has infringed any valid patent claims. The Company has also alleged affirmatively, among other things, that the patent is invalid and that it is not infringed by the Company's manufacture, use, sale or offer to sell its cyclosporine capsules. In September 2002 the court adjourned the scheduled trial of this action and indicated that it would enter judgment in the Company's favor that its cyclosporine product does not infringe Novartis's patent. The court has not yet issued or entered the judgment. 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.

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.

## **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 Registration Statement on Form S-1 (File No. 333-83638) (the Form S-1) and the unaudited interim condensed consolidated financial statements included in Item 1 of this Quarterly Report on Form 10-Q.

### **NINE MONTHS ENDED SEPTEMBER 30, 2001 COMPARED WITH NINE MONTHS ENDED SEPTEMBER 30, 2002**

**Net sales.** Net sales increased 41.3% from \$124.2 million for the nine months ended September 30, 2001 to \$175.5 million for the comparable period in 2002. The net sales increase was attributable primarily to sales of products that were introduced after September 30, 2001. These products include Lovastatin USP, Metformin HCl, Nabumetone, Lisinopril, USP, Lisinopril/HCTZ, Tizanidine HCl, Nizatidine, USP, and a Dextroamphetamine and Amphetamine Mixed Salts product. Other factors impacting sales for the nine months ended September 30, 2002 included an increase in unit volumes of existing products and changes in product mix and unit prices. The change in product mix and price had an unfavorable impact principally due to a decline in both unit volume and selling prices of Fluvoxamine Maleate and a decline in unit volume of Phentermine HCl, USP. Additional competitive activity caused the decrease in Fluvoxamine Maleate unit volume and price. Phentermine HCl, USP sales in the nine months ended September 30, 2001 reflected an increase in unit volume from the refilling of distribution channels following a shortage of the product in the market due to the limited availability of the active pharmaceutical ingredient.

**Gross profit.** Gross profit as a percentage of net sales decreased from 56.8% for the nine months ended September 30, 2001 to 52.3% in the comparable period in 2002. The decrease was primarily due to a decrease in sales and margins for Phentermine HCl, USP and Fluvoxamine Maleate, which had higher gross profit margins than most of the Company's other products in 2001. The Company's gross profit margins are dependent on several factors, including product sales mix, cost, volume and competitive activity.

**Amortization of goodwill and other intangibles.** Amortization of goodwill and other intangibles decreased \$2.5 million from \$5.3 million for the nine months ended September 30, 2001 to \$2.8 million in the comparable period in 2002. The decrease was the result of the adoption of SFAS No. 142 Goodwill and Other Intangible Assets, which the Company adopted on January 1, 2002. Under SFAS No. 142, goodwill and intangibles with indefinite lives are no longer amortized but are evaluated annually for impairment. Therefore, the Company is no longer required to amortize its goodwill and workforce intangible assets.

**Deferred stock appreciation rights compensation.** Deferred stock appreciation rights compensation was \$9.8 million for the nine months ended September 30, 2001. There were no charges for stock appreciation rights in the comparable period



in 2002 because the Company's Stock Appreciation Rights Plan was converted to a Stock Option Plan as of September 30, 2001.

**Other selling, general and administrative.** Other selling, general and administrative expenses increased \$5.6 million from \$19.0 million for the nine months ended September 30, 2001 to \$24.6 million in the comparable period in 2002. As a percentage of sales, other selling, general and administrative expenses decreased 1.3% from 15.3% for the nine months ended September 30, 2001 to 14.0% in the comparable period in 2002. The increase was principally due to increases of \$2.7 million in compensation costs (which included \$0.9 million of deferred compensation), \$2.1 million in insurance, \$0.8 million in freight and \$1.0 million in other expenses, offset by a decrease of \$1.0 million in legal expenses. The decrease in legal expense is the net impact of a decrease in phentermine litigation of \$2.4 million offset by an increase of \$1.4 million in other legal expenses, principally related to patent challenges.

**Research and development.** Research and development expenses increased \$1.9 million from \$8.4 million for the nine months ended September 30, 2001 to \$10.2 million in the comparable period in 2002. The increase was attributable to an increase of \$2.8 million related to generic drug development offset by a decrease of \$0.9 million related to certain basic research contracts unrelated to our business that were transferred in March 2002 to an unrelated entity. The increase in generic drug development costs was principally attributed to increases in costs related to personnel, bio-studies, materials, and supplies. The increase in R&D spending reflects an acceleration of product development activities that are focused on expanding the Company's product line.

**Operating income.** Operating income increased \$26.1 million from \$28.0 million for the nine months ended September 30, 2001 to \$54.1 million for the comparable period in 2002. The increase in operating income was the result of increased sales and gross profit, lower amortization expense and the elimination of deferred stock appreciation rights compensation expense, offset by an increase in other selling, general and administrative and research and development costs.

**Interest income (expense).** Net interest expense decreased \$3.4 million from \$6.7 million for the nine months ended September 30, 2001 to \$3.2 million for the comparable period in 2002. The decrease in interest expense was primarily the result of a decrease in outstanding debt during 2002.

**Taxes on income.** Taxes on income increased \$11.2 million from \$9.6 million for the nine months ended September 30, 2001 to \$20.9 million in the comparable 2002 period. The effective tax rate decreased from 45.2% to 41.0% due to the elimination of non-deductible goodwill amortization in 2002. The increase was the result of higher income during 2002.

**Net income.** Net income increased \$18.3 million from \$11.7 million for the nine months ended September 30, 2001 to \$30.0 million for the comparable 2002 period for the reasons described above.

**THREE MONTHS ENDED SEPTEMBER 30, 2001 COMPARED WITH THREE MONTHS ENDED SEPTEMBER 30, 2002**

**Net sales.** Net sales increased 77.1% from \$42.5 million for the three months ended September 30, 2001 to \$75.4 million for the comparable period in 2002. The net sales increase was attributable primarily to sales of products that were introduced after September 30, 2001. These

products include Lovastatin, USP, Metformin HCl, Nabumetone, Lisinopril, USP, Lisinopril/HCTZ, Tizanidine HCl, Nizatidine, USP, and a Dextroamphetamine and Amphetamine Mixed Salts product. Other factors impacting sales for the three months ended September 30, 2002 included a small net decrease in unit volumes of existing products and changes in product mix and unit prices. The change in unit volume, product mix and price had an unfavorable impact principally due to a decline in selling prices and unit volume of Fluvoxamine Maleate and a decline in unit volume of Phentermine HCl, USP. Additional competitive activity caused the decrease in Fluvoxamine Maleate price. Phentermine HCl, USP sales in the three months ended September 30, 2001 reflected an increase in unit volume from the refilling of distribution channels following a shortage of the product in the market due to the limited availability of the active pharmaceutical ingredient.

**Gross profit.** Gross profit as a percentage of net sales decreased from 55.6% for the three months ended September 30, 2001 to 53.4% in the comparable period in 2002. The decrease was primarily due to a decrease in sales for Phentermine HCl, USP and Fluvoxamine Maleate, products that had higher gross profit margins than most of the Company's other products in 2001. The Company's gross profit margins are dependent on several factors, including product sales mix, cost, volume and competitive activity. Higher production volume in the third quarter 2002 had a modest favorable impact that partially offset an unfavorable change in product mix.

**Amortization of goodwill and other intangibles.** Amortization of goodwill and other intangibles decreased \$0.8 million from \$1.8 million for the three months ended September 30, 2001 to \$0.9 million in the comparable period in 2002. The decrease was the result of the adoption of SFAS No. 142 *Goodwill and Other Intangible Assets*, which the Company adopted on January 1, 2002. Under SFAS No. 142, goodwill and intangibles with indefinite lives are no longer amortized but are evaluated annually for impairment. Therefore, the Company is no longer required to amortize its goodwill and workforce intangible assets.

**Deferred stock appreciation rights compensation.** Deferred stock appreciation rights compensation was \$3.3 million for the three months ended September 30, 2001. There were no charges for stock appreciation rights in the comparable period in 2002 because the Company's Stock Appreciation Rights Plan was converted to a Stock Option Plan as of September 30, 2001.

**Other selling, general and administrative.** Other selling, general and administrative expenses increased \$4.9 million from \$6.5 million for the three months ended September 30, 2001 to \$11.4 million in the comparable period in 2002. As a percentage of sales, other selling, general and administrative expenses decreased 0.1% from 15.2% for the three months ended September 30, 2001 to 15.1% in the comparable period in 2002. The increase was principally due to increases of \$1.5 million in compensation costs (which included \$0.3 million of deferred compensation), \$1.6 million in insurance, \$0.4 million in freight, \$0.8 million in legal expenses, primarily associated with patent challenges, and \$0.6 million in other expenses.

**Research and development.** Research and development expenses increased \$0.7 million from \$3.2 million for the three months ended September 30, 2001 to \$4.0 million in the comparable period in 2002. The increase was attributable to an increase of \$1.4 million related to generic drug development offset by a decrease of \$0.7 million related to certain basic research contracts unrelated to our business that were transferred in March 2002 to an unrelated entity. The



increase in generic drug development costs was principally attributed to increases in costs related to personnel, bio-studies, materials, and supplies. The increase in R&D spending reflects an acceleration of product development activities that are focused on expanding the Company's product line.

**Operating income.** Operating income increased \$15.1 million from \$8.9 million for the three months ended September 30, 2001 to \$24.0 million for the comparable period in 2002. The increase in operating income was the result of increased sales and gross profit, lower amortization expense and the elimination of deferred stock appreciation rights compensation expense, offset by an increase in other selling, general and administrative costs, and research and development costs.

**Interest income (expense).** Net interest expense decreased \$2.3 million going from net interest expense of \$2.2 million for the three months ended September 30, 2001 to net interest income of less than \$0.1 million for the comparable period in 2002. Interest expense decreased \$2.0 million from \$2.3 million for the three months ended September 30, 2001 to \$0.3 million for comparable period in 2002 due to a decrease in outstanding debt. Interest income increased from \$0.1 million for the three months ended September 30, 2001 to \$0.4 million for comparable period in 2002, as investment balances were higher as result of the proceeds from the initial public offering.

**Taxes on income.** Taxes on income increased \$6.9 million from \$3.0 million for the three months ended September 30, 2001 to \$9.9 million in the comparable period in 2002. The effective tax rate decreased from 45.2% to 41.0% due to the elimination of non-deductible goodwill amortization in 2002. The increase was the result of higher income during 2002.

**Net income.** Net income increased \$10.5 million from \$3.6 million for the three months ended September 30, 2001 to \$14.2 million for the comparable period in 2002 for the reasons described above.

## LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were \$17.6 million at December 31, 2001 as compared to \$40.9 million at September 30, 2002. Additionally, the Company has investments in marketable securities of \$19.3 million at September 30, 2002.

At September 30, 2002, the Company's total debt of \$4.4 million was classified as current and is shown under the balance sheet caption "current portion of note payable". The debt represents the remaining balance on a note issued in connection with the acquisition of EHI. At September 30, 2002 the note had a remaining discounted value of \$4.4 million and a face value of \$4.8 million. A Principal payment of \$4.8 million is due on September 30, 2003. The payment is subject to acceleration under the note agreement if certain EBITDA levels are reached. The Company expects to have EBITDA levels in excess of the acceleration thresholds, and expects to pay the balance during the first quarter of 2003.

On February 8, 2002, the Company secured a three-year \$25 million credit facility with a borrowing cost of LIBOR plus 1.5% or the bank's prime rate. The credit facility, which is for working capital purposes, had no outstanding borrowings against it at September 30, 2002.

Stockholders' equity increased from \$47.0 million at December 31, 2001 to \$242.3 million at September 30, 2002. Stockholders' equity was increased by the proceeds from our initial public offering of \$139.2 million, \$25.2 million for the capitalization of Hexal AG debt, earnings of \$30.0 million for the nine months ended September 30, 2002 and \$0.9 million for the amortization of deferred compensation costs.

The Company's initial public offering generated proceeds to the Company of \$139.2 million, net of offering expenses. 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 Eon Holdings, Inc.; and (iii) \$2.0 million has been used for general working capital purposes. At September 30, 2002, the remaining balance of \$60.3 million of the proceeds was available for general corporate purposes.

During the nine months ended September 30, 2002, the Company generated net cash of \$23.3 million.

Operations generated \$0.7 million, which resulted from net earnings of \$30.0 million, non-cash items totaling \$56.7 million and an increase in working capital, which used \$86.1 million. A \$46.8 million provision for accounts receivable allowances is the major non-cash component. The most significant working capital requirement related to a \$72.9 million increase in accounts receivable resulting from higher sales and the timing of customers' payments. Working capital was also used to fund increases in inventory, prepaid expenses and other assets of \$8.7 million, \$14.3 million and \$1.5 million, respectively. The increase in prepaid expenses is primarily related to insurance and income taxes. An increase in accounts payables and accruals of \$11.4 million partially offset the working capital increases.

Outflows from investing activities for this period totaling \$25.3 million were the aggregate of capital expenditures of \$6.0 million and the investment in short-term marketable debt securities of \$19.3 million.





Financing activities generated \$48.0 million for the period. The cash generated from financing activities is the net of \$139.2 million in net proceeds raised in the Company's initial public offering, \$0.8 million of advances received from a related party and a \$0.1 million decrease in restricted cash offset by \$92.1 million of debt repayments.

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 September 2002, the court adjourned the scheduled Novartis trial and indicated that it would enter judgment in the Company's favor stating that the Company's cyclosporine product does not infringe Novartis's patent. The court has not yet issued or entered the judgment. See the Company's Form S-1 and the notes to the Company's nine months unaudited condensed consolidated financial statements.

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, legal defense costs and debt service. 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, capital expenditures and debt payment 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. Our actual results could differ from these estimates under different assumptions or conditions. The Company believes the following accounting policies to be critical:

Revenues 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 our 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 July 2001, the Financial Accounting Standards Board issued SFAS No. 142, Goodwill and Other Intangible Assets. SFAS No. 142 modifies the accounting and reporting for acquired intangible assets at the time of acquisition and in subsequent periods. Intangible assets, which have finite lives, must be amortized over their estimated useful life. Intangible assets with indefinite lives will not be amortized, but evaluated annually for impairment. The Company has completed its impairment assessment and determined that there is no impairment of goodwill or identifiable intangibles upon initial adoption of SFAS No. 142. SFAS No. 142 is effective for fiscal years beginning after December 15, 2001. The value of the Company's existing products is an intangible asset with a finite life that is being amortized over 10 years. The Company's goodwill and workforce intangibles which were being amortized over 15 and 5 year lives, respectively, have not been amortized during the nine-month period ended September 30, 2002. Had this pronouncement been retroactively applied, net income would have increased approximately \$835 and \$2,505, respectively, and diluted earnings per share would have increased \$0.03 per share and \$0.08 per share, respectively, in the three and nine months ended September 30, 2001. In 2002, the Company transferred the net book value of its workforce intangible of \$1,136 to goodwill, resulting in goodwill of \$47,107. The recorded amount of the existing product intangible of \$37,600, before accumulated amortization of \$6,893 as of September 30, 2002, will be amortized through 2010 with annual charges of \$3,760.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets, that replaces SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of. SFAS No. 144 requires that long-lived assets be measured at the lower of carrying amount or fair value, less cost to sell, whether reported in continuing operations or in discontinued operations. SFAS No. 144 is effective for fiscal years beginning after December 15, 2001. The adoption of SFAS No. 144 did not have a material impact on the measurement of its long-lived assets.

In April 2002, the Financial Accounting Standards Board issued SFAS No. 145 Rescission of FAS Nos. 4, 44, and 64, Amendment of SFAS 13, and Technical Corrections as of April 2002 . This Statement amends SFAS No. 13, *Accounting for Leases*, to eliminate an inconsistency between the required accounting for sale-leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to sale-leaseback transactions as well as other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. SFAS No. 145 is effective for fiscal years beginning after December 31, 2002. We do not anticipate that the adoption of SFAS No. 145 will have a material impact on the consolidated financial statements.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146 Accounting for Costs Associated with Exit or Disposal Activities . This Statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force ( EITF ) Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). SFAS No. 146 is effective for fiscal years beginning after December 31, 2002. We do not anticipate that the adoption of SFAS No. 146 will have a material impact on the consolidated financial statements.

### **ITEM 3 - QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

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

As of September 30, 2002, the Company had cash and cash equivalents of \$40.9 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 \$19.3 million in publicly traded debt securities which are subject to market fluctuations.

The Company currently does not have any international operations, 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 September 30, 2002, 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 September 30, 2002. 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 September 30, 2002.

### **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.

## **PART II OTHER INFORMATION**

### **Item 1 - Legal Proceedings**

In 2000, Novartis Pharmaceuticals Corporation filed an action in the United States District Court for the District of Delaware alleging that by manufacturing, using, selling and offering to sell cyclosporine capsules the Company is infringing on a Novartis patent. Novartis 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 Novartis should therefore be awarded the attorney fees it has incurred in the action. The Company has denied that it has infringed any valid patent claims. The Company has also alleged affirmatively, among other things, that the patent is invalid and that it is not infringed by the Company's manufacture, use, sale or offer to sell its cyclosporine capsules. In September 2002 the court adjourned the scheduled trial of this action and indicated that it would enter judgment in the Company's favor that the Company's cyclosporine product does not infringe Novartis's patent. The court has not yet issued or entered the judgment. 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 its profits and cash flows, and could result in it paying damages, costs, expenses and fees that could have a material impact on its financial performance.

### **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 Eon Holdings, Inc.; 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 5 - Other Information**

On October 10, 2002, the Company's Board of Directors appointed Douglas M. Karp and Mark R. Patterson to the Company's Board of Directors. Messrs. Karp and Patterson, along with Frank F. Beelitz, were appointed as members of the Company's Audit Committee. Messrs. Karp and Patterson, along with Thomas Strüngmann and Bernhard Hampl (except with respect to





matters relating to Chief Executive Officer compensation), were appointed as members of the Company's Compensation Committee.

Matthias Hoth, Ph.D. resigned as the Company Vice President, Operations on September 18, 2002. The Company appointed Nitin Sheth, Ph.D., as Vice President of Research and Development on July 3, 2002 and Rathnam Kumar as Vice President of Manufacturing on October 25, 2002.

**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.

November 14, 2002

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

November 14, 2002

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: November 14, 2002

/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: November 14, 2002

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