

MENTOR CORP /MN/  
Form 10-Q  
November 08, 2004

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended September 30, 2004

or

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

For the transition period from \_\_\_\_ to \_\_\_\_

Commission File No. 0-7955

**MENTOR CORPORATION**  
(Exact Name of Registrant as Specified in its Charter)

	Minnesota	41-0950791	
	(State or other jurisdiction of	(IRS Employer Identification No.)	
	incorporation or organization)		

201 Mentor Drive, Santa Barbara, California 93111  
(Address of Principal Executive Offices) (Zip Code)  
Registrant's telephone number including area code: 805/879-6000

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

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

As of November 5, 2004 there were approximately 42,796,358 Common Shares, par value \$.10, outstanding.

**MENTOR CORPORATION**

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**PART I - FINANCIAL INFORMATION****Item 1. Consolidated Financial Statements**

(in thousands)	Mentor Corporation Consolidated Balance Sheets (Unaudited)	
	September 30, 2004	March 31, 2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 127,189	\$ 118,225
Marketable securities	458	193
Accounts receivable, net	102,967	106,016
Inventories	73,449	67,912
Deferred income taxes	23,838	22,488
Prepaid expenses and other	16,750	13,205
Total current assets	344,651	328,039
Property and equipment, net	74,641	77,529
Intangible assets, net	48,320	51,014
Goodwill, net	23,820	23,711
Long-term marketable securities and investments	35,194	8,326
Other assets	10,169	10,160
	\$ 536,795	\$ 498,779

See notes to condensed consolidated financial statements.

Mentor Corporation  
Consolidated Balance Sheets  
(Unaudited)

(in thousands)	<b>September 30, 2004</b>	March 31, 2004
<b><u>Liabilities and shareholders' equity</u></b>		
Current liabilities:		
Accounts payable	\$ 32,429	\$ 37,126
Warranty and related reserves	24,572	23,396
Accrued compensation	19,547	18,212
Short-term bank borrowings	9,385	10,012
Sales returns	11,536	11,797
Deferred revenue	11,654	6,915
Income taxes payable	-	285
Current portion of purchase price related to acquired technologies and acquisitions	1,775	1,864
Interest payable	1,021	1,187
Dividends payable	7,260	6,309
Accrued royalties	708	567
Other	14,921	12,260
Total current liabilities	<b>134,808</b>	129,930
Deferred income taxes	2,569	2,549
Deferred revenue	1,977	-
Long-term accrued liabilities	18,178	17,996
Convertible subordinated notes	<b>150,000</b>	150,000
Shareholders' equity:		
Common Stock, \$.10 par value:		
Authorized - 150,000,000 shares; Issued and outstanding		
42,784,558 shares at September 30, 2004;		
42,059,136 shares at March 31, 2004;	4,278	4,206
Capital in excess of par value	12,780	-
Accumulated other comprehensive income	20,649	19,122
Retained earnings	191,556	174,976
	<b>229,263</b>	198,304
	<b>\$ 536,795</b>	<b>\$ 498,779</b>

See notes to condensed consolidated financial statements.

Mentor Corporation  
 Consolidated Statements of Income  
 Three Months Ended September 30, 2004 and 2003  
 (Unaudited)

(in thousands, except per share data)	<b>2004</b>	Three Months Ended September 30,	2003
Net sales	\$ 108,779		\$ 93,263
Cost of sales	40,638		35,561
Gross profit	68,141		57,702
Selling, general and administrative expense	40,568		33,899
Research and development expense	8,553		7,711
	49,121		41,610
Operating income	19,020		16,092
Interest expense	(1,228)		(149)
Interest income	533		323
Other income, net	5		249
Income before income taxes	18,330		16,515
Income taxes	5,796		5,277
Net income	\$ 12,534		\$ 11,238
Basic earnings per share	\$ 0.29		\$ 0.24
Diluted earnings per share	\$ 0.28		\$ 0.23
Dividends per share	\$ 0.17		\$ 0.15
Weighted average shares outstanding			
Basic	42,548		46,562
Diluted	45,238		48,610

See notes to condensed consolidated financial statements.

Mentor Corporation  
 Consolidated Statements of Income  
 Six Months Ended September 30, 2004 and 2003  
 (Unaudited)

(in thousands, except per share data)	<b>2004</b>	Six Months Ended September 30,	2003
Net sales	<b>\$ 231,211</b>		\$ 198,369
Cost of sales	<b>84,613</b>		74,934
Gross profit	<b>146,598</b>		123,435
Selling, general and administrative expense	<b>83,820</b>		69,578
Research and development expense	<b>16,583</b>		15,254
	<b>100,403</b>		84,832
Operating income	<b>46,195</b>		38,603
Interest expense	<b>(2,636)</b>		(310)
Interest income	<b>948</b>		719
Other income (expense), net	<b>(183)</b>		925
Income before income taxes	<b>44,324</b>		39,937
Income taxes	<b>14,136</b>		12,666
Net income	<b>\$ 30,188</b>		\$ 27,271
Basic earnings per share	<b>\$ 0.71</b>		\$ 0.59
Diluted earnings per share	<b>\$ 0.67</b>		\$ 0.56
Dividends per share	<b>\$ 0.32</b>		\$ 0.17
Weighted average shares outstanding			
Basic	<b>42,356</b>		46,475
Diluted	<b>45,138</b>		48,479

See notes to condensed consolidated financial statements.

Mentor Corporation  
Consolidated Statements of Cash Flows  
Six Months Ended September 30, 2004 and 2003  
(Unaudited)

(in thousands)	2004	2003
<b><u>Operating Activities:</u></b>		
Net income	\$ 30,188	\$ 27,271
Adjustments to derive cash flows from operating activities:		
Depreciation	7,289	6,453
Amortization	2,368	1,658
Deferred income taxes	(1,631)	(2,131)
Tax benefit from exercise of stock options	3,223	2,778
(Gain) loss on sale of assets	1,436	(302)
Imputed interest on long-term liabilities	15	139
(Gain) loss on long-term marketable securities	-	136
Changes in operating assets and liabilities:		
Accounts receivable	3,918	3,164
Inventories	(4,836)	(3,754)
Prepaid income taxes and other current assets	(3,533)	(8,096)
Accounts payable and accrued liabilities	7,364	(326)
Income taxes payable	(267)	(439)
Net cash provided by operating activities	45,534	26,551
<b><u>Investing Activities:</u></b>		
Purchases of property and equipment	(4,829)	(9,089)
Purchases of intangibles	(1,500)	(4,673)
Purchases of marketable securities	(69,028)	(28,244)
Sales of marketable securities	41,854	21,466
Acquisitions, net of cash acquired	-	(7,192)
Net cash used for investing activities	(33,503)	(27,732)
<b><u>Financing Activities:</u></b>		
Repurchase of common stock	-	(8,601)
Proceeds from exercise of stock options	9,628	6,602
Dividends paid	(13,637)	(1,858)
Borrowings (repayments) under line of credit agreements, net	632	(128)
Net cash used for financing activities	(3,377)	(3,985)
Effect of currency exchange rates on cash and cash equivalents	310	370
Increase (decrease) in cash and cash equivalents	8,964	(4,796)
Cash and cash equivalents at beginning of year	118,225	105,840
Cash and cash equivalents at end of period	\$ 127,189	\$ 101,044

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**MENTOR CORPORATION**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**September 30, 2004**

**Note A - Business Activity**

Mentor Corporation (the "Company") was incorporated in April 1969. Unless the context indicates otherwise, when we refer to "Mentor," "we," "us," "our," or the "Company" in this Form 10-Q, we are referring to Mentor Corporation and its subsidiaries on a consolidated basis. We develop, manufacture and market a broad range of products serving the medical specialties market. Our products are utilized by three primary segments, aesthetic and general surgery (plastic and reconstructive surgery), surgical urology, and clinical and consumer healthcare. Aesthetic and general surgery products include surgically implantable prostheses for plastic and reconstructive surgery as well as capital equipment and consumables used for soft tissue aspiration or body contouring (liposuction). Surgical urology products include surgically implantable prostheses for the treatment of impotence, surgically implantable incontinence products, urinary care products and brachytherapy seeds for the treatment of prostate cancer. Clinical and consumer healthcare products include catheters and other products for the management of urinary incontinence and retention.

**Note B - Summary of Significant Accounting Policies**

The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. For those subsidiaries where the Company owns less than 100%, the outside shareholders' interests are treated as minority interests. All inter-company accounts and transactions have been eliminated. Certain prior year amounts in previously issued financial statements have been reclassified to conform to the current year presentation.

**Basis of Presentation**

The financial information for the three and six months ended September 30, 2004 and 2003 is unaudited but includes all adjustments (consisting only of normally recurring accruals, unless otherwise indicated) that the Company considers necessary for a fair presentation of the results of operations for these periods. Interim results are not necessarily indicative of results for the full fiscal year.

**Use of Estimates**

Financial statements prepared in accordance with accounting principles generally accepted in the United States require management to make estimates and judgments that affect amounts and disclosures reported in the financial statements. Actual results could differ from those estimates. A discussion of the Company's significant accounting policies is described in the "Application of Critical Accounting Policies" section of "Management's Discussion and Analysis of Financial Condition and Results of Operations."

**Effects of Recent Accounting Pronouncements**

In July 2004, the Financial Accounting Standards Board (FASB) released draft abstract Emerging Issue Task Force (EITF) Issue No. 04-8, "The Effect of Contingently Convertible Debt on Diluted Earnings per Share," for comment. The objective of this Issue is to provide guidance for whether contingently convertible debt instruments should be included in diluted earnings per share calculations. The draft abstract reflects the Task Force's tentative conclusion that contingently convertible debt should be included in diluted earnings per share calculations regardless of whether or not the trigger price has been reached. In its September meeting, the Task Force confirmed the July conclusion, and the guidance becomes effective December 15, 2004. The impact of the Issue will be to change the diluted earnings per share calculation by increasing net income used in the numerator by the after tax amount of interest expense related to the convertible notes (approximately \$800,000 for the quarter), and increasing weighted average shares outstanding used in the denominator by 5.1 million shares; the number of shares to be issued upon full conversion of the convertible notes. The effect would decrease diluted earnings per share by \$.02 cents per share for the quarter ended September 30, 2004. We expect to adopt the guidance in the quarter ended December 31, 2004.

In March 2004, the Financial Accounting Standards Board (FASB) approved the consensus reached on the EITF Issue No. 03-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments." The objective of this Issue is to provide guidance for identifying impaired investments. EITF 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. The accounting provisions of EITF 03-1 are effective for all reporting periods beginning after June 15, 2004, while the disclosure requirements are effective only for annual periods ending after June 15, 2004. We have evaluated the impact of the adoption of EITF 03-1 and do not believe it will be significant to our results of operations or financial position.

**Note C - Interim Reporting**

The Company's three quarterly interim reporting periods are each thirteen-week periods ending on the Friday nearest the end of the third calendar month of each calendar quarter. The fiscal year end remains March 31<sup>st</sup>. To facilitate ease of presentation, each interim period is shown as if it ended on the last day of the appropriate calendar month. The actual dates for each of the three interim quarters-end are shown below:

	<u>Fiscal 2005</u>	<u>Fiscal 2004</u>
First Quarter	July 2, 2004	June 27, 2003
Second Quarter	October 1, 2004	September 26, 2003
Third Quarter	December 31, 2004	January 2, 2004

The accompanying unaudited condensed consolidated financial statements for the three month and six month periods ended September 30, 2004 and 2003 have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting only of normally recurring accruals, unless otherwise indicated) considered necessary for a fair presentation of the results of operations for the indicated periods have been included. Certain amounts recorded in previous periods have been reclassified to conform to the current period presentation. Operating results for the three month and six month periods ended September 30, 2004 are not necessarily indicative of the results for the full fiscal year.

The balance sheet at March 31, 2004 has been derived from the audited financial statements as of that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

The condensed consolidated financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended March 31, 2004.

**Note D - Cash Equivalents, Marketable Securities, and Long-Term Marketable Securities and Investments**

All highly liquid investments with maturities of three months or less at the date of purchase are considered to be cash equivalents.

The Company considers its marketable securities available-for-sale as defined in Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities." Realized gains and losses, and declines in value considered to be other than temporary, are included in income. The cost of securities sold is based on the specific identification method. For short-term marketable securities, there were no material realized or unrealized gains or losses, nor were there any material differences between estimated fair values, based on quoted market prices, and the costs of securities in the investment portfolio as of September 30, 2004, and March 31, 2004. Short-term investments, except auction rate securities, mature between three months and one year from the purchase date. The Company's short-term marketable securities consist primarily of money market mutual funds, U.S. state and municipal government and government agency obligations, auction rate securities, and investment grade corporate obligations including commercial paper. Auction rate securities carry interest or dividend rates that reset every 28 days but have contractual maturities of greater than one year.

The Company's long-term marketable securities and investments include investments in Federal Home Loan Bank and Mortgage Association bonds (FHLA bonds) with maturities of two to four years.

Available-for-sale investments at September 30, 2004 were as follows:

(in thousands)	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash balances	\$ 38,333	\$ -	\$ -	\$ 38,333
Money market mutual funds	88,856	-	-	88,856
Marketable equity securities	144	-	(8)	136
U.S., state and municipal agency obligations	35,305	-	(67)	35,238
Corporate debt securities	278	-	-	278
<b>Total available-for-sale investments</b>	<b>\$ 162,916</b>	<b>-</b>	<b>\$ (75)</b>	<b>\$ 162,841</b>
Included in cash and cash equivalents	127,189	-	-	127,189
Included in current marketable securities	458	-	-	458
Included in long-term marketable securities and investments	35,269	-	(75)	35,194
<b>Total available-for-sale investments</b>	<b>\$ 162,916</b>	<b>\$ -</b>	<b>\$ (75)</b>	<b>\$ 162,841</b>

Available-for-sale investments at March 31, 2004 were as follows:

(in thousands)	Adjusted Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Cash balances	\$ 19,139	\$ -	\$ -	\$ 19,139
Bank time deposits	-	-	-	-
Money market mutual funds	99,086	-	-	99,086
Marketable equity securities	56	-	(8)	48
U.S., State and Municipal agency obligations	8,193	-	-	8,193
Corporate debt securities	278	-	-	278
<b>Total available-for-sale investments</b>	<b>\$ 126,752</b>	<b>-</b>	<b>(8)</b>	<b>\$ 126,744</b>
Included in cash and cash equivalents	118,225	-	-	118,225
Included in current marketable securities	193	-	-	193
Included in long-term marketable securities and investments	8,334	-	(8)	8,326
<b>Total available-for-sale investments</b>	<b>\$ 126,752</b>	<b>\$ -</b>	<b>\$ (8)</b>	<b>\$ 126,744</b>

#### Note E - Inventories

Inventories are stated at the lower of cost or market, cost determined by the first-in, first-out (FIFO) method. The Company writes down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions.

Inventories at September 30, 2004 and March 31, 2004 consisted of:

(in thousands)	September 30,	March 31
Raw materials	\$ 14,209	\$ 13,050
Work in process	12,587	11,572
Finished goods	46,653	43,290
	<b>\$ 73,449</b>	<b>\$ 67,912</b>

**Note F - Property and Equipment**

Property and equipment is stated at cost. Depreciation is based on the useful lives of the properties and computed using the straight-line method. Buildings are depreciated over 30 years, furniture and equipment over 3 to 10 years and leasehold improvements over the shorter of their estimated remaining lives or lease terms. Significant improvements and betterments are capitalized while maintenance and repairs are charged to operations as incurred.

Property and equipment at September 30, 2004 and March 31, 2004 consisted of:

(in thousands)	September 30,	March 31,
Land	\$ 566	\$ 561
Buildings	24,883	24,534
Leasehold improvements	24,849	23,776
Furniture, fixtures and equipment	106,196	103,242
Construction in progress	3,662	3,811
	160,156	155,924
Less accumulated depreciation	(85,515)	(78,395)
	\$ 74,641	\$ 77,529

**Note G - Warranties**

The Company provides an accrual for the estimated cost of product warranties and product liability claims at the time revenue is recognized. Such accruals are based on estimates, which are based on relevant factors such as historical experience, the warranty period, estimated costs, levels of insurance and insurance retentions, identified product quality issues, if any, and to a limited extent, information developed by the insurance company using actuarial techniques. The Company assesses the adequacy of these accruals periodically and adjusts the amounts as necessary based on actual experience and changes in future expectations.

Information on changes in the Company's accrued warranties and related reserves are as follows:

(in thousands)	Six Months Ended September 30,	
	2004	2003
Beginning warranty and related reserve	\$ 23,396	\$ 19,989
Costs of warranty claims	(2,122)	(1,930)
Accruals for product warranties	3,298	4,063
Ending warranty and related reserves	\$ 24,572	\$ 22,122

**Note H - Other Comprehensive Income**

The components of comprehensive income are listed below:

(in thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003	2004	2003
Net income	\$ 12,534	\$ 11,238	\$ 30,188	\$ 27,271
Foreign currency translation adjustment	1,613	826	1,571	5,858
Unrealized (losses) on marketable securities and investment activities, net	117	25	(44)	146
Comprehensive income	\$ 14,264	\$ 12,089	\$ 31,715	\$ 33,275

**Note I - Stock Options**

The Company has granted options to key employees and non-employee directors under its Amended 2000 Long-Term Incentive Plan (2000 Plan) and 1991 Plan. Options granted under both plans are exercisable in four equal annual installments beginning one year from the date of grant, and expire ten years from the date of grant. Options are granted at the fair market value as of the date of grant. Options to purchase 732,750 shares of common stock at \$32.23 per share were granted during the quarter ended June 30, 2004. Options to purchase 47,500 shares of common stock at \$34.58 per share were granted during the quarter ended September 30, 2004.

Stock option exercise prices are set at the fair market value of the Company's common stock on the date of grant and the related number of shares granted is fixed at that point in time. Therefore, under the principles of Accounting Principles Board (APB) Opinion 25, the Company does not recognize compensation expense associated with the grant of stock options. SFAS 123 "Accounting for Stock-Based Compensation", requires the use of an option valuation model to provide supplemental information regarding options granted after fiscal 1995. Pro forma information regarding net income and earnings per share shown below were determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The estimated fair value of the options is amortized ratably over the options' vesting period. As required by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123", the following table shows the estimated effect on net income and earnings per share if the Company had applied the fair value recognition provision of SFAS 123 to stock-based employee compensation. The Company's pro forma information is as follows:

(in thousands except per share data)	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003	2004	2003
Net income: as reported <sup>(1)</sup>	\$ 12,534	\$ 11,238	\$ 30,188	\$ 27,271
Deduct: compensation expense fair value method	(1,787)	(1,899)	(3,555)	(3,319)
Net income: pro forma	\$ 10,747	\$ 9,339	\$ 26,633	\$ 23,952
Basic earnings per share: as reported	\$ .29	\$ .24	\$ .71	\$ .59
Basic earnings per share: pro forma	\$ .25	\$ .20	\$ .63	\$ .51
Diluted earnings per share: as reported	\$ .28	\$ .23	\$ .67	\$ .56
Diluted earnings per share: pro forma	\$ .24	\$ .20	\$ .59	\$ .50

<sup>(1)</sup> Net income as reported includes no compensation expense associated with stock grants.

**Note J - Income Taxes**

The effective rate of corporate income taxes was 31.9% and 31.7% for the six-month periods ended September 30, 2004 and 2003, respectively.

**Note K - Earnings per Share**

Basic earnings per share is computed by dividing net income available to common shareholders by the weighted average number of shares of the Company's common shares outstanding during the period. Diluted earnings per share is calculated in the same manner as basic earnings per share except that the number of shares outstanding is increased by potentially dilutive common shares outstanding during the period. Potentially dilutive common shares consist of shares issuable under the terms of employee stock options, warrants, and the 2¾% convertible subordinated notes. A reconciliation of weighted average shares outstanding, used to calculate basic earnings per share, to weighted average shares outstanding assuming dilution, used to calculate diluted earnings per share, follows:

(in thousands)	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003	2004	2003
Weighted average outstanding shares: basic	<b>42,548</b>	46,562	<b>42,356</b>	46,475
Shares issuable through exercise of stock options	<b>2,690</b>	2,048	<b>2,782</b>	2,004
Weighted average outstanding shares: diluted	<b>45,238</b>	48,610	<b>45,138</b>	48,479

Shares issuable through stock options are determined using the treasury stock method. Certain potential shares issuable under the terms of employee stock options were excluded from the computation of diluted earnings per share since their exercise prices were greater than the market prices of the common shares during or at the end of the period, and accordingly, their effect would have been anti-dilutive. Shares potentially issuable upon the conversion of the 2¾% convertible subordinated notes were excluded as the market prices of the common shares did not reach the specific levels for the specified times required in order for the notes to allow conversion during the period. Additionally, during the quarter ended September 30, 2004, the price of the Company's stock did not exceed the specific strike prices of the convertible bond hedge or the warrants for the specified time required that the Company entered into to reduce the potential dilution from any conversion of the notes. Both the bond hedge and the warrants transaction may be settled at the Company's option, either in cash or shares, and expire on January 1, 2009.

**Note L - Share Repurchase Program**

The Company has a stock repurchase program, primarily to offset the dilutive effect of our employee stock option program, to provide liquidity to the market and to reduce the overall number of shares outstanding. All shares repurchased under the program are retired and are no longer deemed to be outstanding. In May 1999, the Board of Directors authorized the repurchase of 9.2 million shares of our stock. Each year shares have been repurchased including 1.4 million shares for \$22.3 million and 1.5 million shares for \$18.7 million in the years ended March 31, 2003 and 2002, respectively. At March 31, 2003, 1.8 million shares were remaining under this authorization. On July 31, 2003 the Board of Directors increased the authorized number of shares to be repurchased from 1.8 million to 4 million shares. On December 5, 2003, the Board of Directors increased the authorized number of shares to be repurchased by 5 million shares from 2.5 million to 7.5 million shares. During fiscal 2004, 5.4 million shares were repurchased for \$135.8 million and 3.6 million shares remained authorized for repurchase as of March 31, 2004 and September 30, 2004. The timing of repurchases is subject to market conditions, cash availability, and blackout periods during which the Company is restricted from repurchasing shares. There is no guarantee that shares authorized for repurchase by the Board will ultimately be repurchased. There were no share repurchases during the three-month and six-month periods ending September 30, 2004.

**Note M - Acquisitions**

**South Bay Medical LLC**

On January 19, 2001, the Company purchased the assets of South Bay Medical LLC (South Bay), a company focused on the development of a new computer-based workstation and automated cartridge-based needle loading system for use in brachytherapy procedures. The acquisition was accounted for as a purchase with the results of operations included in the Company's financial statements from the date of acquisition. The Company paid \$2 million in cash and issued restricted common stock valued at \$4 million on the date of purchase. Additional purchase price payments will be made to South Bay over the next several years as workstation sales are made. The net present value of these amounts is recorded at September 30, 2004, in current accrued liabilities (\$775,000) and in long-term accrued liabilities (\$10,550,000) as the Company believes it is probable these payments will be paid.

**Prosurg, Inc.**

In December 2001, the Company entered into several agreements with Prosurg, Inc., to acquire certain patent rights and obtain a source of supply of a bio-absorbable co-polymer for \$2 million in cash and up to an additional \$2 million upon the achievement of certain milestones. The purchase price was allocated to intangible assets and the net present value of these amounts is recorded at September 30, 2004, in accrued liabilities (\$1,000,000) and in long-term accrued liabilities (\$1,000,000) as the Company believes it is probable these payments will be paid.

**A-Life Ltd.**

On August 25, 2003, the Company completed the acquisition of A-Life Ltd, which has developed a hyaluronic acid based dermal filler product, from Vitrolife, AB. The acquisition was valued at \$7.5 million; net of cash acquired, and was paid from existing cash balances. The purchase price was allocated to the tangible and intangible net assets acquired on the basis of their respective fair values on the acquisition date. The purchase price was preliminarily allocated to accounts receivable of \$36,000, other assets of \$349,000, production equipment of \$393,000 and intangible assets of \$6,821,000, net of accrued liabilities of \$123,000.

**Note N - Goodwill & Intangible Assets**

In 2001, the FASB issued SFAS No. 142, "Goodwill and Other Intangible Assets". SFAS No. 142 was effective for the Company as of April 1, 2002. SFAS No. 142 specifies the financial accounting and reporting for acquired goodwill and other intangible assets. Goodwill and intangible assets that have indefinite useful lives are no longer to be amortized, but rather are to be tested for impairment annually or more frequently if impairment indicators arise. None of the Company's intangible assets have an indefinite life. Intangible assets with finite lives continue to be amortized over their useful lives ranging from 3-20 years on a straight line basis. Goodwill and intangible assets have been recorded at either incurred or allocated cost. Allocated costs were based on respective fair values at the date of acquisition.

Upon the adoption of SFAS No. 142, the Company reassessed the remaining amortization periods of intangible assets acquired on or before June 30, 2001, and assigned all goodwill to reporting units for impairment testing. The impairment tests involve the use of both estimates of fair value for the Company's reporting units as well as discounted cash flow assumptions. Impairment tests were performed at adoption and in the fourth quarter of fiscal years 2004 and 2003 and no impairment was noted as a result of these analyses.

As of September 30, 2004 and March 31, 2004, accumulated amortization of intangible assets was \$16.6 million and \$14.2 million respectively.

### Note O - Long-term Debt

On December 22, 2003, the Company completed an offering of \$150 million of convertible subordinated notes due January 1, 2024 pursuant to Rule 144A under the Securities Act of 1933. The notes bear interest at 2¾% per annum and are convertible into shares of the Company's common stock at a conversion price of \$29.27 per share and are subordinated to all existing and future senior debt.

Holders of the notes may convert their notes only if any of the following conditions is satisfied:

- during any fiscal quarter prior to January 1, 2019, if the closing price of the Company's common stock for at least 20 trading days in the 30 consecutive trading day period ending on the first trading day of such fiscal quarter is more than 120% of the conversion price per share of the Company's common stock on such trading day;
- any business day on or after January 1, 2019, if the closing price of the Company's common stock on the immediately preceding trading day is more than 120% of the conversion price per share of the Company's common stock on such trading day;
- during the five business day period after any five consecutive trading day period if the average of the trading prices of the notes for such five consecutive trading day period is less than 98% of the average of the conversion values of the notes during such period, subject to certain limitations;
- if the Company calls the notes for redemption; or
- if the Company makes certain significant distributions to holders of its common stock or the Company enters into specified corporate transactions.

At an initial conversion price of \$29.289, each \$1,000 principle amount of notes will be convertible into 34.1425 shares of common stock. As a result of the Company's recent dividend increase the conversion price has been adjusted to \$29.27, and each \$1,000 principle amount will be convertible into 34.1632 shares of common stock.

Concurrent with the issuance of the convertible subordinated notes, the Company entered into a convertible note hedge and a warrants transaction with respect to its common stock, the exposure for which is held by Credit Suisse First Boston LLC. Both the note hedge and the warrants transaction may be settled at the Company's option either in cash or shares and expire January 1, 2009. The convertible note hedge and warrants transactions combined are intended to reduce the potential dilution from conversion of the notes by effectively increasing the conversion price per share to \$39.43. The cost of the note hedge and the proceeds of warrants sale have been included in stockholder's equity in accordance with the guidance in Emerging Issues Task Force No. 00-19, "Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in a Company's own Stock." Any proceeds received or payments made upon termination of these instruments will be recorded in stockholders equity.

**Note P - Business Segment Information**

The Company's operations are principally managed and reported on a product basis. There are three reportable segments: aesthetic and general surgery, surgical urology, and clinical and consumer healthcare. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies except that certain expenses such as interest and certain corporate expenses are not allocated to the segments.

The aesthetic and general surgery products segment consists primarily of breast implants, tissue expanders and the Company's body contouring (liposuction) equipment and disposables. The surgical urology segment includes penile implants, surgical incontinence products, and brachytherapy seeds for the treatment of prostate cancer. The clinical and consumer healthcare segment includes catheters and other disposable products for the management of urinary incontinence and retention.

Selected financial information for the Company's reportable segments for the three-month and six-month periods ended September 30, 2004 and 2003, and as of September 30, 2004 and March 31, 2004 is as follows:

(in thousands)	Three Months Ended September 30, 2004		Six Months Ended September 30, 2004	
		2003		2003
<b>Net sales</b>				
Aesthetic and General Surgery	\$ 54,322	\$ 47,199	\$ 119,866	\$ 102,702
Surgical Urology	30,374	23,903	62,286	51,992
Clinical and Consumer Healthcare	24,083	22,161	49,059	43,675
Total consolidated revenues	\$ 108,779	\$ 93,263	\$ 231,211	\$ 198,369

(in thousands)	Three Months Ended September 30, 2004		Six Months Ended September 30, 2004	
		2003		2003
<b>Operating profit</b>				
Aesthetic and General Surgery	\$ 18,390	\$ 15,987	\$ 43,936	\$ 35,777
Surgical Urology	1,168	(748)	3,446	788
Clinical and Consumer Healthcare	2,645	3,111	5,658	6,433
Total reportable segments	\$ 22,203	\$ 18,350	\$ 53,040	\$ 42,998

(in thousands)	Three Months Ended September 30, 2004		Six Months Ended September 30, 2004	
		2003		2003
<b>Operating income</b>				
Reportable segments	\$ 22,203	\$ 18,350	\$ 53,040	\$ 42,998
Corporate operating expenses	(3,183)	(2,258)	(6,845)	(4,395)
Interest expense	(1,228)	(149)	(2,636)	(310)
Interest income	533	323	948	719
Other income	5	249	(183)	925
Income before income taxes	\$ 18,330	\$ 16,515	\$ 44,324	\$ 39,937

(in thousands)	As of	
	September 30, 2004	March 31, 2004
<b>Identifiable assets</b>		
Aesthetic and General Surgery	\$ 134,490	\$ 135,199
Surgical Urology	117,803	114,937
Clinical and Consumer Healthcare	74,825	76,695
Total reportable segments	\$ 327,118	\$ 326,831

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

*Cautionary Statement:*

*The following discussion and analysis should be read in conjunction with our Unaudited Condensed Consolidated Financial Statements and related Notes thereto contained elsewhere in this Report. The information contained in this Quarterly Report on Form 10-Q is not a complete description of our business or the risks associated with an investment in our securities. We urge you to carefully review and consider the various disclosures made by us in this Report and in our other reports filed with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K for the year ended March 31, 2004, and subsequent reports on Forms 10 Q and 8 K, which discuss our business in greater detail.*

*The section entitled "Risk Factors" set forth below, and similar discussions in our other SEC filings, discuss some of the important risk factors that may affect our business, results of operations and financial condition. These risks, in addition to the other information in this Report and in our other filings with the SEC, should be carefully considered before deciding to purchase, hold or sell our securities.*

*All statements included in this Report, other than statements or characterizations of historical fact, are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements include, but are not limited to, statements concerning:*

- *our anticipated growth strategies;*
- *our anticipated sales, expenses and taxes for fiscal 2005*
- *our intention to introduce or seek regulatory approval for new products;*
- *our ability to continue to meet FDA and other regulatory requirements;*
- *our anticipated outcomes of litigation and regulatory reviews;*
- *our ability to replace sources of supply without disruption or regulatory delay;*
- *our accounting estimates, assumptions and judgments, the market acceptance and performance of our products, the competitive nature of and anticipated growth in our markets;*
- *our ability to consummate acquisitions and integrate their operations successfully; and*
- *the need for additional capital.*

*These forward-looking statements are based on our current expectations, estimates and projections about our industry, management's beliefs, and certain assumptions made by us. Forward-looking statements can often be identified by words such as "anticipates," "expects," "intends," "plans," "predicts," "projects," "believes," "seeks," "estimates," "may," "will," "should," "would," "could," "potential," "continue," "ongoing," "guidance," and similar expressions, and variations or negatives of these words. In addition, any statements that refer to expectations, projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. These forward-looking statements speak only as of the date of this Report and are based upon the information available to us at this time. Such information is subject to change, and we will not necessarily inform you of such changes. These statements are not guarantees of future results and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statement as a result of various factors, some of which are listed under the section "Risk Factors" below. We undertake no obligation to revise or update publicly any forward-looking statement for any reason.*

Company Overview

Founded in 1969, we are a leading supplier of medical products for the global healthcare market. We develop, manufacture and market a broad range of products serving the medical specialties market. Our products are utilized by three primary segments, aesthetic and general surgery (plastic and reconstructive surgery), surgical urology, and clinical and consumer healthcare.

Our aesthetic and general surgery products include surgically implantable prostheses for plastic and reconstructive surgery, as well as capital equipment and consumables used for soft tissue aspiration or body contouring (liposuction). Our surgical urology products include surgically implantable prostheses for the treatment of impotence, surgically implantable incontinence products, urinary care products and brachytherapy seeds for the treatment of prostate cancer. Our clinical and consumer healthcare products include catheters and other products for the management of urinary incontinence and retention.

We employ approximately 2,000 people around the world and are headquartered in Santa Barbara, California, with manufacturing and research operations in the United States, France, the Netherlands and the United Kingdom. We also purchase finished products and certain raw material components from third party manufacturers and suppliers. The cost of goods sold represents raw materials, labor and overhead, and the cost of third party finished products. Gross margins may fluctuate from period to period due to changes in the selling prices of our products, the mix of products sold, changes in the cost of third party finished products, raw materials, labor and overhead and manufacturing efficiencies or inefficiencies.

In addition to our strong domestic presence, we export most of our product lines, principally to Canada, Western Europe, Central and South America, and the Pacific Rim. Products are sold through our direct international sales offices in Canada, the United Kingdom, Germany, France, Japan, Benelux, Australia, Spain, Portugal and Italy, as well as through independent distributors in other countries.

We employ specialized domestic sales forces for our aesthetic surgery, body contouring, and urologic specialties, which includes our women's health, erectile dysfunction, prostate brachytherapy and clinical and consumer healthcare product lines

Our selling, general and administrative expense incorporates the expenses of our sales and marketing organization and the general and administrative expenses necessary to support the global corporation. Our sales and marketing expenses consist primarily of salaries, commissions, and marketing program costs. General and administrative expenses incorporate the costs of finance, human resources, information services, legal and insurance costs.

Our research and development expenses are comprised of the following types of costs incurred in performing clinical development and research and development activities: salaries and benefits, allocated overhead, clinical trial and related clinical manufacturing costs, regulatory costs, contract services, and other outside costs. We also conduct research on materials technology, product design and product improvement.

### Recent Developments

On October 25, 2003, we completed the acquisition of Inform Solutions Inc., now doing business as Mentor Practice Development Services located in San Diego, California. Mentor Practice Development Services is a leading provider of comprehensive integrated practice management software and revenue enhancement services to the plastic surgery industry. We paid cash for the acquisition and committed to several milestone payments over the ensuing three years based upon sales and earnings. We expect that the software and consulting revenues generated by Mentor Practice Development Services will not be substantial. We do, however, generally anticipate that the software and services Mentor Practice Development Services offers will assist our plastic surgery customers to better manage their practices, resulting in growth of our related product sales.

On December 10, 2003 we completed a licensing agreement with the Wisconsin Alumni Research Foundation ("WARF"), which gives us the exclusive manufacturing and marketing rights to the proprietary botulinum toxin technology developed at the University of Wisconsin-Madison. In exchange, we paid cash and committed to royalty payments based upon future sales, and future payments based upon developmental milestones. We do not expect any revenues from products utilizing this technology in fiscal year 2005 or fiscal year 2006, as the products will require additional research, clinical studies and regulatory approvals before they can be marketed.

On December 22, 2003, we completed an offering of \$150 million of convertible subordinated notes due January 1, 2024 pursuant to Rule 144A under the Securities Act of 1933. The notes bear interest at 2<sup>3</sup>/<sub>4</sub>% per annum and are convertible into shares of our common stock at an adjusted conversion price of \$29.27 per share and are subordinated to all existing and future senior debt.

### **APPLICATION OF CRITICAL ACCOUNTING POLICIES**

Management's Discussion and Analysis of Financial Condition and Results of Operations addresses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our estimates and judgments. We base our estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management has identified the critical accounting policies to be those related to revenue recognition, accounts receivable, inventories, warranties and related reserves, and goodwill and intangible asset impairment. These accounting policies are discussed in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and notes to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2004.

**RESULTS OF OPERATIONS****For the three-month period ended September 30, 2004 compared to the three-month period ended September 30, 2003**

Our quarterly results reflect slight seasonality, as the fiscal quarter ending September 30 tends to have lower breast implant revenues than the other three quarters. This is primarily due to patients delaying elective surgical procedure, such as breast augmentation, until after the summer vacation season, particularly in Europe.

The following table sets forth certain data from the Consolidated Statements of Income expressed as a percentage of net sales for the periods indicated:

	For the Three Months Ended		For the Six Months Ended	
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Net sales	100.0 %	100.0 %	100.0 %	100.0 %
Cost of sales	37.4 %	38.1 %	36.6 %	37.8 %
Gross profit	62.6 %	61.9 %	63.4 %	62.2 %
Selling, general and administrative expense	37.3 %	36.4 %	36.3 %	35.1 %
Research and development expense	7.9 %	8.3 %	7.2 %	7.7 %
Operating income	17.4 %	17.2 %	19.9 %	19.4 %
Interest expense	(1.3)%	(0.1)%	(1.1)%	(0.1)%
Interest income	0.7 %	0.3 %	0.4 %	0.4 %
Other income (expense), net	0.0 %	0.3 %	(0.1)%	0.5 %
Income before income taxes	16.8 %	17.7 %	19.1 %	6.4 %
Income taxes	5.3 %	5.7 %	6.1 %	6.4 %
Net income	11.5 %	12.0 %	13.0 %	13.8 %

**Sales**

Sales for the three-month period ended September 30, 2004 increased 16.6% to \$108.8 million from \$93.3 million for the same quarter in the prior year. Foreign exchange rate movements, primarily the strengthening of the Euro, had a favorable year-to-year impact on international sales of \$3.1 million for the three-month period. We continue to expect total sales to increase in fiscal 2005 at a low double digit rate over sales in fiscal 2004.

(in thousands)	Sales by Principal Product Line For the Three Months Ended September 30,			For the Six Months Ended September 30,		
	2004	2003	Percent Change	2004	2003	Percent Change
Aesthetic & General Surgery Products	\$ 54,322	\$ 47,199	15.1%	\$ 119,866	\$ 102,702	16.7%
Surgical Urology Products	30,374	23,903	27.1%	62,286	51,992	19.8%
Clinical & Consumer Healthcare Products	24,083	22,161	8.7%	49,059	43,675	12.3%
	\$ 108,779	\$ 93,263	16.6%	\$ 231,211	\$ 198,369	16.6%

Sales of aesthetic and general surgery products increased 15.1% to \$54.3 million for the quarter ended September 30, 2004, from \$47.2 million in the same period in the prior year. Approximately \$0.7 million or 1.5% of this increase is attributable to the favorable impact of foreign exchange rate movements and the balance is primarily attributable to organic growth of our silicone gel breast implants and associated products used in reconstruction surgeries. Total sales of breast implant products increased 12.2% to \$46.9 million for the quarter from \$41.8 million in the same period in the prior year. Increased sales were driven by strong performance in the augmentation and reconstruction markets both domestically and internationally. Although we try to avoid competing on price, we continue to see competitive price pressure in both the domestic and international markets. Sales of body contouring products increased 10.2% to \$3.9 million for the quarter from \$3.5 million in the same period in the prior year. Liposuction continues to be the leading surgical cosmetic procedure in the United States, and sales of our capital equipment, associated disposable products, and higher average selling prices were the leading contributors to body contouring sales growth for the quarter ended September 30, 2004. Although both breast implant and body contouring revenue increased, we believe sales were negatively impacted by the severe weather conditions during the quarter in the Southeast United States, which is a significant market for us. Other aesthetic products sales increased 87% to \$3.6 million for the quarter from \$1.9 million in the same period of the prior year as a result of increased revenue from physician participation in our "Extreme Makeover" direct to consumer television advertising program and revenue from our October 2003 acquisition of Mentor Practice Development Services.

Sales of surgical urology products increased 27.1% to \$30.4 million for the quarter ended September 30, 2004, from \$23.9 million in the same period in the prior year. The reorganization of our urology sales force, which was completed in early 2004, continues to benefit sales. Sales of women's health care products increased 83% to \$5.2 million for the three months ended September 30, 2004 compared to \$2.8 million in the prior year. This increase was primarily attributable to our ObTape™ sling product, which was introduced in the United States during August 2003 for the treatment of stress urinary incontinence. Penile implant sales increased 8.8% to \$6.2 million from \$5.7 million in the comparable period of the prior year due to continued market acceptance of our Titan® penile device in Europe, and to the reduction in patients sampling competitive drug therapies for erectile dysfunction, which had negatively impacted prior year sales. Brachytherapy product sales increased by 10.1% to \$3.8 million for the quarter ended September 30, 2004, from \$3.4 million in the same period in the prior year as a result of higher unit sales and improved average selling prices. Sales of our disposable urinary care products increased by \$3.2 million to \$15.1 million for the quarter ended September 30, 2004, compared to \$11.9 million in the prior year. The favorable impact of foreign exchange rate variations also increased segment revenue \$1.4 million for the quarter ended September 30, 2004 compared to the prior year.

Sales of clinical and consumer healthcare products increased 8.7% or \$1.9 million to \$24.1 million for the quarter ended September 30, 2004 from \$22.2 million in the same period of the prior year. Sales of catheters increased 11.6% or \$1.4 million to \$13.5 million for the quarter ended September 30, 2004 from \$12.1 million for the comparable period in the prior year. This increase resulted from a shift to our premium product categories which all have premium pricing as well as a favorable impact of foreign exchange rate variations of \$1.0 million for this segment.

### **Gross profit**

Gross profit increased to 62.6% of net sales for the quarter ended September 30, 2004, compared to 61.9% in the comparable period in the prior year. Gross profit for aesthetic and general surgery products improved to 74.1% of net sales, or \$40.2 million for the three-month period ending September 30, 2004, up from 73% of net sales in the comparable period in the prior year. This increase in gross profit of \$5.7 million is primarily attributable to manufacturing efficiencies at our Texas and Netherlands facilities. Gross profit for surgical urology products improved to 54.0% of net sales for the quarter ended September 30, 2004, compared to 51.4% of net sales in the same period in the prior year. This improvement is primarily due to increased sales of women's health care products, which have a higher gross margin than other products in this segment, and the licensing of our trans-obturator method patent. Gross profit for healthcare products decreased to 47.8% of net sales for the quarter ended September 30, 2004, compared to 49.5% of net sales for the quarter ended September 30, 2003. This decrease is due to manufacturing inefficiencies at our foreign manufacturing facilities.

### **Selling, General and Administrative**

Selling, general and administrative expenses were \$40.6 million, or 37.3% of net sales for the quarter ended September 30, 2004, compared to \$33.9 million or 36.4% for the comparable quarter in the prior year. The increase as a percentage of net sales is primarily the result of increased information technology support, higher regulatory expense related to the silicone gel PMA filing, higher legal expenses from ongoing and recently concluded litigation, recent acquisitions, and to a lesser extent increased support of sales, and our recently launched direct to consumer television advertising program. The increase in general and administrative expense was partially offset by lower product warranty and product liability expenses. For the fiscal year ending March 31, 2005, we expect sales, general and administrative expense to be in the range of 35% to 37% of net sales.

### **Research and Development**

Research and development expenses for the quarter ended September 30, 2004 were \$8.6 million compared to \$7.7 million a year ago, or approximately 8% of net sales for each period. Research and development spending for the quarter ended September 30, 2004 was primarily to support key strategic product development programs including our silicone gel breast implant PMA, the botulinum toxin program, the Hyalite dermal filler program, and the continued development of automated manufacturing technologies. We expect the level of spending on research and development activities to be in the range of 7% to 8% of net sales for the fiscal year ending March 31, 2005.

### **Interest and Other Income and Expense**

Interest expense increased approximately \$1.0 million to \$1.2 million for the quarter ended September 30, 2004, compared to \$.2 million in the same period of the prior year. The increase is the result of additional interest on our \$150 million in convertible subordinated notes issued in December 2003, carrying a coupon rate of 2 3/4%. The remaining interest expense is interest on balances outstanding under our foreign lines of credit.

### **Income Taxes**

The effective rate of corporate income taxes for the three-months ended September 30, 2004, was 31.6% as compared to 32.0% for the comparable period in the prior year. We expect our effective tax rate to be in the range of 32% to 33% for the fiscal year ending March 31, 2005.

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**Net Income and Earnings Per Share**

Net income for the quarter ended September 30, 2004 increased 11.6% to \$12.5 million from \$11.2 million in the comparable period in the prior year. Diluted earnings per share increased 21.7% to \$0.28 for the quarter, compared to \$0.23 for the comparable period last year. As a result of our stock repurchase program, we have fewer shares outstanding resulting in a positive impact on the year-over-year quarterly comparison of diluted earning per share.

**For the six-month periods ended September 30, 2004 compared to the six-month periods ended September 30, 2003.**

**Sales**

Sales increased 16.6%, or \$32.8 million to \$231.2 million for the six months ended September 30, 2004, compared to \$198.4 million for the same period in the prior year. Foreign exchange rate movements, primarily the strengthening of the Euro, had a favorable year-to-year impact on international sales of \$5.9 million for the six month period.

Sales of aesthetic and general surgery products increased 16.7%, or \$17.2 million to \$119.9 million for the six-month period ended September 30, 2004, compared to \$102.7 million for the same period in the prior year. Approximately \$1.5 million of the increase is attributable to the favorable impact of foreign exchange rates and the balance is due to organic growth in unit sales. Sales of breast implants increased \$13 million or 14.2% to \$104.3 million for the six months ended September 30, 2004, compared to \$91.3 million for the same period in the prior year. Body contouring product sales increased 21.1% to \$8.6 million for the six-month period ended September 30, 2004, from \$7.1 million for the comparable period in the prior year. Increases in body contouring product sales are primarily attributable to increased liposuction procedural volumes as awareness and acceptance of this procedure increases. Although both breast implant and body contouring revenue increased, we believe sales were negatively impacted by the severe weather conditions during the quarter ended September 30, 2004 in the Southeast United States, which is a significant market for us. Other product sales increased by 26% to \$6.9 million for the six months ended September 30, 2004, compared to \$5.5 million the same period in the prior year as a result of increased revenue from physician participation in our "Extreme Makeover" direct to consumer television advertising program and revenue from our October 2003 acquisition of Mentor Practice Development Services.

Sales of surgical urology products increased 19.8%, or \$10.3 million to \$62.3 million for the six month period ended September 30, 2004, compared to \$52 million for the same period in the prior year. This growth primarily resulted from the reorganization of our urology sales force, which was completed in early 2004 and led to improved selling focus and higher sales productivity. The increases in sales were primarily attributable to a \$5.1 million increase in sales of our women's health care products and a \$4.1 million increase in sales of our disposable urinary care products. This increase in sales was primarily attributable to our ObTape™ sling product, which was introduced in the United States during August 2003 for the treatment of stress urinary incontinence. Brachytherapy product sales increased 7% to \$7.6 million for the six months ended September 30, 2004 compared to \$7.1 million for the same period in the prior year as a result of higher unit sales and improved average selling prices. Foreign exchange rate fluctuations favorably impacted sales by \$2.5 million.

Sales of clinical and consumer healthcare products increased 12.3%, or \$5.3 million to \$49 million for the six month period ended September 30, 2004 compared to \$43.7 million for the same period in the prior year. Sales of our catheter products increased \$4.2 million or 18.6% to \$26.8 million for the six month period ended September 30, 2004, from \$22.6 million for the same period of the prior year. Sales of other disposable homecare and ostomy products increased 5.2% to \$22.2 million for the quarter ended September 30, 2004, from \$21.1 million in the comparable period of the prior year. This increase resulted from a shift to our premium product categories which all have premium pricing as well as a favorable impact of foreign exchange rate variations of \$1.9 million for this segment.

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**Gross profit**

Gross profit for the six-months ended September 30, 2004, improved to 63.4% of net sales from 62.2% for the same period in the prior year. Gross profit for aesthetic and general surgery products improved to 74.5% of net sales, or \$89.3 million for the six-month period ending September 30, 2004, up from 72.1% of net sales in the comparable six-month period in the prior year. This increase in gross profit of \$15.3 million is primarily attributable to manufacturing efficiencies at our Texas and Netherlands facilities. Gross profit for surgical urology products for the six-month period ended September 30, 2004 improved to 53.9% of net sales compared to 52.6% of net sales for the same period in the prior year. The improvement in the gross profit percentage is primarily due to increased sales of women's health care products, which have a higher gross margin than other products in this segment, and the licensing of our trans-obturator method patent. Gross profit for clinical and consumer healthcare products for the six-month period ended September 30, 2004, decreased to 48.4% of net sales compared to 50.6% in the prior year. This decrease is due to manufacturing inefficiencies at our foreign manufacturing facilities.

**Selling, General and Administrative**

Selling, general and administrative expense increased to 36.3% of net sales, or \$83.8 million for the six-month period ended September 30, 2004, compared to 35.1% or \$69.6 million in the comparable period of the prior year. The increase as a percentage of net sales is primarily the result of increased information technology support, higher regulatory expense related to the silicone gel PMA filing, higher legal expenses from ongoing and recently concluded litigation, recent acquisitions, and to a lesser extent increased support of sales, and our recently launched direct to consumer television advertising program. The increase in general and administrative expense was partially offset by lower product warranty and product liability expenses.

**Research and Development**

Research and development expenses for the six-month period ended September 30, 2004 decreased from 7.7% to 7.2% as a percent of net sales, and were \$16.6 million compared to \$15.3 million for the comparable period a year ago. Research and development spending primarily supports key strategic product development programs including our silicone gel breast implant PMA, the botulinum toxin program, the Hyalite dermal filler program, and the continued development of automated manufacturing technologies. During the first quarter of fiscal 2005 we recorded a \$0.8 million charge related to the termination of a brachytherapy development project and related automated manufacturing equipment.

**Interest and Other Income and Expense**

Interest expense for the six-month period ended September 30, 2004 increased to \$2.6 from \$0.3 million in the comparable period in the prior year. Approximately \$2.1 million of the expense relates to the \$150 million in convertible subordinated notes issued in December 2003 with a coupon rate of 2 3/4%. The remaining interest expense is interest on balances outstanding under our foreign lines of credit.

**Income Taxes**

The effective rate of corporate income taxes for the six-months ended September 30, 2004 was 31.9% as compared to 31.7% for the comparable period in the prior year.

**Net Income and Earnings Per Share**

Net income for the six-month period ended September 30, 2004 increased 10.6% to \$30.2 million from \$27.3 million in the comparable period in the prior year. Diluted earnings per share increased 19.6% to \$.67 for the six-month period compared to \$.56 for the comparable period last year. As a result of our stock repurchase program, we have fewer shares outstanding, resulting in a positive impact on the year over year six month comparison of diluted earning per share.

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**LIQUIDITY AND CAPITAL RESOURCES**

Our balance sheet reflected cash, cash equivalents and short-term marketable securities of \$128 million at September 30, 2004, compared to \$118 million at March 31, 2004. During the first quarter of fiscal 2005 we invested \$25 million of cash into long-term marketable securities, primarily Federal Home Loan Bank and Federal National Mortgage Association notes to increase our interest income on our cash reserves. Our cash provided by operating activities and the proceeds of our convertible notes has been our primary recurring source of funds, and this is expected to continue. Our working capital was \$210 million at September 30, 2004, compared to \$198 million at March 31, 2004. We generated \$46 million of cash from operating activities during the six months ended September 30, 2004, compared to \$27 million during the same period the previous year. Approximately \$3 million of the increase was attributable to increased net income, \$1.5 million was attributable to additional amortization and depreciation expense and \$1.7 million was attributable to non-cash losses on asset disposals for the six-month period ended September 30, 2004. The timing of income tax payments added \$5 million to operating cash flows and an increase in accounts payable and accrued liabilities added approximately \$8 million for the six months ended September 30, 2004, compared to the same period in the prior year.

During the six months ended September 30, 2004, we invested approximately \$4.8 million in property and equipment, primarily for production equipment purchases. We anticipate additional investments of approximately \$10 million during the remainder of fiscal 2005 to continue facility improvements and to purchase production equipment.

We receive cash from the exercise of employee stock options. Employee stock option exercises provided \$9.6 million of cash during the six months ended September 30, 2004 compared to \$6.6 million in the same period the previous year. Proceeds from the exercise of employee stock options will vary from period to period based primarily upon fluctuations in the market value of our common shares relative to the exercise price of such options, among other factors.

We have a stock repurchase program, primarily to offset the dilutive effect of our employee stock option program, to provide liquidity to the market, and to reduce the overall number of shares outstanding. All shares repurchased under the program are retired and are no longer deemed to be outstanding. At September 30, 2004, 3.6 million shares remained authorized for repurchase. The timing of repurchases is subject to market conditions, cash availability, and blackout periods during which we are restricted from repurchasing shares. There is no guarantee that shares authorized for repurchase by the Board will ultimately be repurchased. There were no share repurchases under this program for the six month period ending September 30, 2004.

In January 2001, we completed the acquisition of the assets of South Bay Medical, LLC. The total consideration included \$2 million in cash, 470,586 restricted shares of our common stock having a fair market value of \$4 million, and \$13.6 million to be paid in cash or our common stock over the next several years. These future payments are recorded as an acquisition obligation payments liability of \$11.4 million at September 30, 2004. Approximately \$5.9 million of the future acquisition obligation payments is to be paid in shares of our common stock valued at fair market value on the date of issuance, over several years based on the achievement of unit sale milestones.

In December 2001, we entered into several agreements with Prosurge, Inc. to purchase certain patent rights and to secure a supply of product. The total consideration included \$2.0 million in cash and \$1.7 million in short and long-term payments due over the next several years. The future payments have been recorded as an acquisition obligation liability at net present value and will increase with imputed interest to \$2.0 million, due over the next several years, based on the achievement of certain milestones.

On September 9, 2003, we entered into several transactions to acquire from AMI, LLC, the exclusive license, marketing and distribution rights for certain product technology, and intellectual property rights, as well as, a related supply agreement with Prosurge, Inc. We have paid \$4.5 million in cash and issued 133,630 restricted shares of our common stock valued at fair market value of \$3 million. We anticipate making additional payments of \$3.0 million upon the completion of certain developmental and regulatory milestones, expected to be achieved over the next several years.

On October 25, 2003, we acquired Inform Solutions, Inc., now doing business as Mentor Practice Development Services, for total consideration of \$3 million in cash. The agreement commits us to make additional payments totaling up to \$1.7 million based upon achievement of future sales and earnings thresholds over 3 years.

On December 22, 2003, we completed an offering of \$150 million of convertible subordinated notes due January 1, 2024 pursuant to Rule 144A under the Securities Act of 1933. The notes bear interest at 2<sup>3</sup>/<sub>4</sub>% per annum and are convertible into shares of our common stock at an adjusted conversion price of \$29.27 per share and are subordinated to all existing and future senior debt. Concurrent with the issuance of the convertible subordinated notes, we entered into a convertible bond hedge and warrants transactions with respect to our common stock, the exposure for which is held by Credit Suisse First Boston LLC for a net cash payment of \$18.5 million. Both the bond hedge and the warrants transactions may be settled at our option either in cash or net shares and expire January 1, 2009. The convertible bond hedge and warrants transactions combined are intended to reduce the potential dilution from conversion of the notes by effectively increasing the conversion price per share to \$39.43.

In September 2004, the Board of Directors increased the quarterly dividend rate from \$.15 per share to \$.17 per share. It is our intent to continue to pay dividends for the foreseeable future subject to, among other things, Board approval, cash availability, debt restrictions and alternative cash needs. At the current annual dividend rate of \$.68 per share, the aggregate annual dividend would be approximately \$28 million.

We had a secured line of credit for borrowings up to \$25 million ("Credit Agreement"), which accrued interest at the prevailing prime rate or 1.75% over LIBOR, at our discretion. The Credit Agreement expired in September 2004 and we are currently renegotiating a new agreement which we expect will have similar terms. The Credit Agreement included certain covenants that, among other things, limited the dividends we could pay and required maintenance of certain levels of tangible net worth and debt service ratios. At September 30, 2004, we had three commercial letters of credit totaling \$2.0 million.

In addition, in February 2001, we established several lines of credit with local foreign lenders to facilitate operating cash flow needs at our foreign subsidiaries. These credit lines are at market rates of interest, unsecured, are guaranteed by us, and total \$7.1 million, of which \$5.4 million was outstanding, and \$1.7 million was available at September 30, 2004.

In fiscal 2002, we established a line of credit of \$6.5 million to finance the construction of a new facility in Leiden, the Netherlands. The borrowings accrue interest at EURIBOR plus 0.75% and are secured by the new facility and other assets in The Netherlands. At September 30, 2004, \$4 million was outstanding and \$2.5 million was available under this line.

At September 30, 2004, our total short-term borrowings under all lines of credit were \$9.4 million and the weighted-average interest rate was 2.99%. The total amount of additional borrowings available to us under all lines of credit was \$4.2 million and \$28.1 million at September 30, 2004 and March 31, 2004, respectively.

We enter into various product and intellectual property acquisitions and business combinations. In connection with some of these activities, we agree to make payments to third parties when specific milestones are achieved, such as receipt of regulatory approvals or achievement of performance or operational targets.

We do not have any off-balance sheet arrangements that are currently material or reasonably likely to be material to our financial position or results of operations.

Our principal source of liquidity at September 30, 2004 consisted of \$128 million in cash, cash equivalents and short-term marketable securities, plus \$35 million of highly liquid marketable securities accounted for as long term assets, plus \$6.2 million available under our existing lines of credit. We believe that funds generated from operations, our cash, cash equivalents and marketable securities and funds available under line of credit agreements will be adequate to meet our working capital needs and capital expenditure investment requirements and commitments for the foreseeable future. However, it is possible that we may need to raise additional funds to finance unforeseen requirements or to consummate acquisitions of other business, products or technologies. Additional funds could be raised by selling equity or debt securities to the public or to selected investors, or by borrowing money from financial institutions. In addition, even though we may not need additional funds, we may still elect to sell additional equity or debt securities or obtain credit facilities for other reasons. We may not be able to obtain additional funds on terms that would be favorable to us, or at all. If funds are raised by issuing additional equity securities or convertible debt securities, the ownership percentage of existing shareholders would be reduced. In addition, the equity or debt securities issued by us may have rights, preferences or privileges senior to those of our common stock.

### **Risk Factors**

#### **Forward-Looking Information Under the Private Securities Litigation Reform Act of 1995**

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. The Act was designed to encourage companies to provide prospective information about them without fear of litigation. The prospective information must be identified as forward-looking and must be accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those projected in the statements. The statements about our business, plans, strategies, intentions, expectations and prospects contained throughout this document are based on current expectations. These statements are forward-looking and actual results may differ materially from those predicted as of the date of this report in the forward-looking statements, which involve risks and uncertainties. In addition, past financial performance is not necessarily a reliable indicator of future performance and investors should not use historical performance to anticipate results or future period trends. We undertake no obligation to revise or update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

Our business faces many risks. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations. If any of the events or circumstances described in the following risks actually occurs, our business, financial condition or results of operations could suffer and the trading price of our common stock or our convertible notes could decline. You should consider the following risks before deciding to invest in our common stock or convertible notes.

#### ***Significant product liability claims or product recalls may force us to pay substantial damage awards and other expenses that could exceed our accruals and insurance coverage.***

The manufacture and sale of medical devices exposes us to significant risk of product liability claims. In the past, and currently, we have had a number of product liability claims relating to our products, and we may be subject to additional product liability claims in the future, some of which may have a negative impact on our business. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Some manufacturers that suffered such claims in the past have been forced to cease operations or even to declare bankruptcy. Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues, or heightened regulatory scrutiny that would warrant a recall of some of our products and could result in exposure to additional product liability claims.

***We are subject to substantial government regulation, which could materially adversely affect our business.***

The production and marketing of our products and our ongoing research and development, pre-clinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad. Most of the medical devices we develop must undergo rigorous pre-clinical and clinical testing and an extensive regulatory approval process before they can be marketed. This process makes it longer, more difficult and more costly to bring our products to market, and we cannot guarantee that any of our products will be approved. The pre-marketing approval process can be particularly expensive, uncertain and lengthy, and a number of devices for which FDA approval has been sought by other companies have never been approved for marketing. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record-keeping procedures. If we do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution.

Delays in, withdrawal, or rejection of FDA or other government entity approval of our products, may also adversely affect our business. Such delays or rejection may be encountered due to, among other reasons, government or regulatory delays, lack of efficacy during clinical trials, unforeseen safety issues, slower than expected rate of patient recruitment for clinical trials, inability to follow patients after treatment in clinical trials, inconsistencies between early clinical trial results and results obtained in later clinical trials, varying interpretations of data generated by clinical trials, or changes in regulatory policy during the period of product development in the U.S. and abroad. In the U.S., there has been a continuing trend of more stringent FDA oversight in product clearance and enforcement activities, causing medical device manufacturers to experience longer approval cycles, greater risk and uncertainty, and higher expenses. Internationally, there is a risk that we may not be successful in meeting the quality standards or other certification requirements. Even if regulatory approval of a product is granted, such approval may entail limitations on uses for which the product may be labeled and promoted, or may prevent us from broadening the uses of our current products for different applications. In addition, we may not receive FDA approval to export our products in the future, and countries to which products are to be exported may not approve them for import.

Our manufacturing facilities also are subject to continual governmental review and inspection. The FDA has stated publicly that compliance with manufacturing regulations will be scrutinized more strictly. A governmental authority may challenge our compliance with applicable federal, state and foreign regulations. In addition, any discovery of previously unknown problems with one of our products or facilities may result in restrictions on the product or the facility, including withdrawal of the product from the market or other enforcement actions.

From time to time, legislative or regulatory proposals are introduced that could alter the review and approval process relating to medical devices. It is possible that the FDA or other governmental authorities will issue additional regulations which would further reduce or restrict the sales of our present or proposed products. Any change in legislation or regulations that govern the review and approval process relating to our current and future products could make it more difficult and costly to obtain approval for new products, or to produce, market, and distribute existing products.

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***If we are unable to continue to develop and commercialize new technologies and products, we may experience a decrease in demand for our products or our products could become obsolete.***

The medical device industry is highly competitive and is subject to significant and rapid technological change. We believe that our ability to develop or acquire new technologies is crucial to our success. We are continually engaged in product development, improvement programs and required clinical studies to maintain and improve our competitive position. Any significant delays in the above or termination of our clinical trials would materially and adversely affect our development and commercialization timelines. We cannot guarantee that we will be successful in enhancing existing products, or in developing or acquiring new products or technologies that will timely achieve regulatory approval.

There is also a risk that our products may not gain market acceptance among physicians, patients and the medical community generally. The degree of market acceptance of any medical device or other product that we develop will depend on a number of factors, including demonstrated clinical safety and efficacy, cost-effectiveness, potential advantages over alternative products, and our marketing and distribution capabilities. Physicians will not recommend our products if clinical and other data or other factors do not demonstrate their safety and efficacy compared to other competing products, or if our products do not best meet the particular needs of the individual patient.

Our products compete with a number of other medical products manufactured by major companies, and may also compete with new products currently under development by others. On January 8, 2004 the FDA released new Draft Guidance for Saline, Silicone Gel, and Alternative Breast Implants. This new draft guidance has additional requirements from the FDA's previously issued guidance document dated February 2003. We completed our PMA application to the FDA for the pre-market approval for our silicone gel-filled implants for breast augmentation, reconstruction and revision in December 2003, using the earlier guidance document provided by the FDA. The FDA has indicated that our PMA "is sufficiently complete to permit a substantive review and is, therefore, suitable for filing." Any change in FDA guidance, such as that announced on January 8<sup>th</sup> by the FDA, may delay or may otherwise adversely affect our application or its review or approval by the FDA. A delay, denial, or "not approvable" response by the FDA would have a material adverse affect on our commercialization timelines, competitive position and ultimately our revenue and operating results. In August we amended our PMA based on the FDA draft guidance and responded to other issues raised by the FDA. We continue to address their questions and the process may require substantial time and expense based on the nature of the questions with no assurances of success. If our competitor gains FDA approval to market its competitive products before we do, our competitive position may suffer. If our new products do not achieve significant market acceptance, or if our current products are not able to continue competing successfully in the changing market, our sales and earnings may not grow as much as expected, or may even decline.

***If we suffer negative publicity concerning the safety of our products, our sales may be harmed and we may be forced to withdraw products.***

Physicians and potential patients may have a number of concerns about the safety of our products, including our breast and other implants, whether or not such concerns have a basis in generally accepted science or peer-reviewed scientific research. Negative publicity-whether accurate or inaccurate-concerning our products could reduce market or governmental acceptance of our products and could result in decreased product demand or product withdrawal. In addition, significant negative publicity could result in an increased number of product liability claims, whether or not these claims are supported by applicable law.

***If changes in the economy and consumer spending reduce consumer demand for our products, our sales and profitability could suffer.***

Certain elective procedures, such as breast augmentation, body contouring, and surgical treatment for male impotence are typically not covered by insurance. Adverse changes in the economy may cause consumers to reassess their spending choices and reduce the demand for these surgeries and could have an adverse effect on consumer spending. This shift could have an adverse effect on our sales and profitability.

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***If we are unable to implement new information technology systems, our ability to manufacture and sell products, maintain regulatory compliance and manage and report our business activities may be impaired, delayed or diminished, which would cause substantial business interruption and loss of sales, customers and profits.***

We are in the process of implementing an enterprise resource planning system that will be our primary business management system for nearly all of our businesses worldwide. Many other companies have had severe problems with computer system implementation of this nature and scope. We are using a controlled project plan and we believe we have assigned adequate staffing and other resources to the project to ensure its successful implementation; however there is no assurance that the design will meet our current and future business needs or that it will operate as designed. We are heavily dependent on such computer systems, and any failure or delay in the system implementation would cause a substantial interruption to our business, additional expense, and loss of sales, customers, and profits.

***If we are unable to acquire companies, businesses or technologies as part of our growth strategy or to successfully integrate past acquisitions, our growth, sales and profitability could suffer.***

A significant portion of our recent growth has been the result of acquisitions of other companies, businesses and technologies. We intend to continue to acquire other businesses and technologies to facilitate our future business strategies, although there can be no assurance that we will be able to identify appropriate acquisition candidates, consummate transactions or obtain agreements with terms favorable to us. Further, once a business is acquired, any inability to integrate the business, failure to retain and develop its workforce, or establish and maintain appropriate communications, performance expectations, regulatory compliance procedures, accounting controls, and reporting procedures could adversely affect our future sales and earnings.

***If our intellectual property rights do not adequately protect our products or technologies, others could compete against us more directly, which would hurt our profitability.***

Our success depends in part on our ability to obtain patents or rights to patents, protect trade secrets, operate without infringing upon the proprietary rights of others, and prevent others from infringing on our patents, trademarks and other intellectual property rights. We will be able to protect our intellectual property from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents, trademarks or licenses. Patent protection generally involves complex legal and factual questions and, therefore, enforceability of patent rights cannot be predicted with certainty; thus, any patents that we own or license from others may not provide us with adequate protection against competitors. Moreover, the laws of certain foreign countries do not recognize intellectual property rights or protect them to the same extent as do the laws of the United States.

In addition to patents and trademarks, we rely on trade secrets and proprietary know-how. We seek protection of these rights, in part, through confidentiality and proprietary information agreements. These agreements may not provide sufficient protection or adequate remedies for violation of our rights in the event of unauthorized use or disclosure of confidential and proprietary information. Failure to protect our proprietary rights could seriously impair our competitive position.

***If third parties claim we are infringing their intellectual property rights, we could suffer significant litigation or licensing expenses or be prevented from marketing our products.***

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of others. However, regardless of our intent, our technologies may infringe upon the patents or violate other proprietary rights of third parties. In the event of such infringement or violation, we may face expensive litigation and may be prevented from selling existing products and pursuing product development or commercialization.

***We depend on single and sole source suppliers for certain raw materials and licensed or manufactured products and the loss of any supplier could adversely affect our ability to manufacture or sell many of our products.***

We currently rely on single or sole source suppliers for raw materials, including silicone, used in many of our products. In the event that they cannot meet our requirements, we cannot guarantee that we would be able to obtain a sufficient amount of quality raw materials in a timely manner. We also depend on third party manufacturers for components and licensed products, including our women's health products and our palladium brachytherapy seed product. If there is a disruption in the supply of these products, our sales and profitability would be adversely affected.

***Our international business exposes us to a number of risks.***

More than one-third of our sales are derived from international operations. Accordingly, any material decrease in foreign sales would have a material adverse effect on our overall sales and profitability. Most of our international sales are denominated in Euros, British Pounds, Canadian Dollars or U.S. Dollars. Depreciation or devaluation of the local currencies of countries where we sell our products may result in our products becoming more expensive in local currency terms, thus reducing demand, which could have an adverse effect on our operating results. Our operations and financial results may be adversely affected by other international factors, including:

- foreign government regulation of medical devices;
- product liability, intellectual property and other claims;
- new export license requirements;
- political or economic instability in our target markets;
- trade restrictions;
- changes in tax laws and tariffs;
- managing foreign distributors and manufacturers;
- managing foreign branch offices and staffing; and
- competition.

***Health care reimbursement or reform legislation could materially affect our business.***

If any national health care reform or other legislation or regulations are passed that imposes limits on the amount of reimbursement for certain types of medical procedures or products, or on the number or type of medical procedures that may be performed, or that has the effect of restricting a physician's ability to select specific products for use in patient procedures, such changes could have a material adverse effect on the demand for our products. Our revenues depend largely on U.S. and foreign government health care programs and private health insurers reimbursing patients' medical expenses. Physicians, hospitals, and other health care providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payers for the cost of procedures using our products. In the U.S., there have been, and we expect that there will continue to be, a number of federal and state legislative and regulatory proposals to implement greater governmental control over the healthcare industry and its related costs. These proposals create uncertainty as to the future of our industry and may have a material adverse effect on our ability to raise capital or to form collaborations. In a number of foreign markets, the pricing and profitability of healthcare products are subject to governmental influence or control. In addition, legislation or regulations that impose restrictions on the price that may be charged for healthcare products or medical devices may adversely affect our sales and profitability.

***If our use of hazardous materials results in contamination or injury, we could suffer significant financial loss.***

Our manufacturing and research activities involve the controlled use of hazardous materials. We cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or environmental discharge, we may be held liable for any resulting damages, which may exceed our financial resources and any applicable insurance coverages.

***Future changes in financial accounting standards may cause adverse unexpected revenue or expense fluctuations and affect our reported results of operations.***

A change in accounting standards could have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. The Financial Accounting Standards Board ("FASB") has issued a Proposed Statement of Financial Accounting Standards ("SFAS"), Share-Based Payment, an amendment of FASB Statements Nos. 123 and 95 ("Exposure Draft"). The Exposure Draft would eliminate the ability to account for share-based compensation transactions using Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees, and generally would require that such transactions be accounted for using a fair-value-based method, and the resulting cost recognized in the financial statements. The approval of this Exposure Draft or any changes requiring that we record compensation expense in the statement of operations for employee stock options using the fair value method could have a significant negative effect on our reported results. New pronouncements and varying interpretations of existing pronouncements have occurred and may occur in the future. Changes to existing rules or current practices may adversely affect our reported financial results of our business.

***Our reported earnings per share may be more volatile because of the contingent conversion provision of the notes.***

Holders of our 2¾% convertible notes are entitled to convert the notes into our common stock during any fiscal quarter prior to January 1, 2019, if the closing price of our common stock for at least 20 trading days in the 30 consecutive trading day period ending on the first trading day of such fiscal quarter is more than \$35.15, if we have called the notes for redemption, or upon other specified events. Until one of these contingencies is met, the shares underlying the notes are not included in the calculation of our basic or diluted earnings per share. Should a contingency be met, diluted earnings per share would be expected to decrease as a result of the inclusion of the underlying shares in the diluted earnings per share calculation. Volatility in our common stock price could cause this condition to be met in one quarter and not in a subsequent quarter, increasing the volatility of our diluted earnings per share.

***Hedging transactions and other transactions may affect the value of the notes.***

In connection with the original issuance of our 2¾% convertible notes in December 2003, we entered into convertible note hedge and warrant transactions with respect to our common stock with Credit Suisse First Boston International, an affiliate of Credit Suisse First Boston LLC, the initial purchaser of the notes, to reduce the potential dilution from conversion of the notes up to a price of our common stock of \$39.43 per share. In connection with these hedging arrangements, Credit Suisse First Boston International, and/or its affiliates, has taken and, we expect, will continue to take positions in our common stock in secondary market transactions and/or will enter into various derivative transactions. Such hedging arrangements could adversely affect the market price of our common stock. In addition, the existence of the notes may encourage short selling in our common stock by market participants because the conversion of the notes could depress the price of our common stock.

***Litigation may harm our business or otherwise distract our management.***

Substantial, complex or extended litigation could cause us to incur large expenditures and distract our management, and could result in significant monetary or equitable judgments against us. For example, lawsuits by employees, patients, customers, licensors, licensees, suppliers, distributors, stockholders, or competitors could be very costly and could substantially disrupt our business. Disputes from time to time with such companies or individuals are not uncommon, and we cannot assure that we will always be able to resolve such disputes out of court or on terms favorable to us.

***Our publicly-filed SEC reports are reviewed by the SEC from time to time and any significant changes required as a result of any such review may result in material liability to us and have a material adverse impact on the trading price of our common stock.***

The reports of publicly-traded companies are subject to review by the SEC from time to time for the purpose of assisting companies in complying with applicable disclosure requirements and to enhance the overall effectiveness of companies public filings, and comprehensive reviews by the SEC of such reports are now required at least every three years under the Sarbanes-Oxley Act of 2002. SEC reviews often occur at the time companies file registration statements such as the registration statement we filed in connection with our convertible note offering, but reviews may also be initiated at any time by the SEC. While we believe that our previously filed SEC reports comply, and we intend that all future reports will comply in all material respects with the published rules and regulations of the SEC, we could be required to modify or reformulate information contained in prior filings as a result of an SEC review. Any modification or reformulation of information contained in such reports could be significant and result in material liability to us and have a material adverse impact on the trading price of our common stock.

***Our operating results may fluctuate substantially, and could precipitate unexpected movement in the price of our common stock and convertible notes.***

Our common stock trades on the New York Stock Exchange under the symbol "MNT." On September 30, 2004, the closing price of our common stock on the New York Stock Exchange was \$34.29 per share. On December 22, 2003, we completed an offering of \$150 million of convertible subordinated notes ("notes") due January 1, 2024 pursuant to Rule 144A under the Securities Act of 1933. The notes bear interest at 2<sup>3</sup>/<sub>4</sub>% per annum, are convertible into shares of our common stock at an adjusted conversion price of \$29.27 per share and are subordinated to all existing and future senior debt. The market prices of our stock and convertible securities are subject to significant fluctuations in response to the factors set forth above and other factors, many of which are beyond our control such as changes in pricing policies by our competitors and the timing of significant orders and shipments.

Such factors, as well as other economic conditions, may adversely affect the market price of our securities, including our common stock and the notes. There could be periods in which we experience shortfalls in revenue and/or earnings from levels expected by securities analysts and investors, which could have an immediate and significant adverse effect on the trading price of our securities, including our common stock and our convertible notes.

**Item 3. Quantitative And Qualitative Disclosures About Market Risk**

There have been no material changes in our exposure to market risk as reported in Item 7A in our Annual Report on Form 10-K for the fiscal year ended March 31, 2004.

**Item 4. Controls and Procedures**

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

We carried out an evaluation under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2004, the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2004.

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2004 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II – OTHER INFORMATION**

**Item 1. Legal Proceedings**

In February 2004, we filed a patent infringement suit in the United States District Court for the District of Minnesota against American Medical Systems, Inc. ("AMS"). The suit alleged that AMS was inducing infringement and contributing to the infringement of our United States Patent No. 6,638,211 B2 ("211 Patent"), a patent involving a method for the treatment of urinary incontinence in women, by AMS offering for sale and selling its Monarc Subfacial Hammock in the United States. The suit sought compensatory and treble damages. AMS subsequently served us with a Complaint for declaratory judgment, which AMS had filed earlier in the same District Court, seeking a declaration that AMS did not infringe any valid claim of the '211 Patent and that the claims of the '211 Patent were invalid and unenforceable against AMS. Because the cases involved the same facts, they were assigned to the same judge. On September 13, 2004, during the early stages of the litigation, we entered into a settlement agreement with AMS under which both parties agreed to dismiss their respective lawsuits. Under the settlement agreement, the parties agreed to concurrently enter into a non-exclusive cross-license agreement covering patents and patent applications related to the field of female pelvic health. Under the cross-license agreement, AMS made a one-time payment to us in the amount of \$2.5 million for access to the '211 Patent.

On March 4, 2004, John H. Alico, et. al., d/b/a PTF Royalty Partnership ("PTF") filed a lawsuit against us in the Business Litigation Session of the Superior Court of Massachusetts, Suffolk County in which PTF alleges, among other things, breach of a merger agreement that involved our acquisition of Mentor O&O, Inc. ("O&O"), an unrelated entity at that time, which was dated as of March 14, 1990 ("Merger Agreement") (prior to the merger, O&O had no affiliation with us). PTF alleges that we breached the terms of the Merger Agreement by failing to exert commercially reasonable and diligent efforts to obtain approval by the FDA for a product used for the treatment of urinary incontinence and by failing to accurately account for and pay royalties due thereunder. PTF seeks damages in excess of \$18 million, which is the maximum amount of royalties PTF could have received under the Merger Agreement. After almost ten years, in or about January 2001, we elected to discontinue pursuing FDA approval for the product, given the FDA's repeated and ongoing concerns regarding the product's use for urinary incontinence. We believe we complied with all of our obligations under the Merger Agreement, which specifically provided that we were under no obligation to engage in efforts or expenditures in respect of the product which we in good faith deemed to be inadvisable based on various factors. Accordingly, we intend to vigorously defend the lawsuit. Dr. Richard Young, a member of our Board of Directors since March 1990, is a partner of PTF and is a named plaintiff in the above action. Dr. Young was a shareholder and principal of O&O prior to the merger and was instrumental in facilitating the transition after the merger.

In addition, in the ordinary course of our business we experience other varied types of claims that sometimes result in litigation or other legal proceedings. Although there can be no certainty, we do not anticipate that any of these proceedings will have a material adverse effect on us.

**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Submission of Matters to a Vote of Security Holders**

At the Company's 2004 Annual Meeting of Shareholders held on September 15, 2004, the following proposals were presented :

(1) A proposal to increase the number of directors by four from seven to eleven. The proposal received 39,594,478 votes for, and 76,852 against ratification. There were 114,450 abstentions and four broker non-votes.

(2) The proposal to elect the following individuals to the Board of Directors of the Company to serve until the next annual meeting, or until their successors are elected, was approved as follows:

Name of Director	Votes For	Votes Withheld
Christopher J. Conway	39,149,785	216,610
Walter W. FASTER	37,202,475	2,163,920
Eugene G. Glover	38,896,303	470,092
Michael Nakonechny	37,213,468	2,152,927
Ronald J. Rossi	37,235,130	2,131,265
Jeffrey W. Ubben	37,247,395	2,119,000
Dr. Richard W. Young	22,627,101	16,739,294
Michael L. Emmons	39,258,104	108,291
Joshua H. Levine	39,137,431	228,964
Adel Michael	39,119,867	246,528
Joseph E. Whitters	39,262,391	104,004

(3) A proposal to ratify the appointment of Ernst & Young LLP to act as independent auditors of the Company for the fiscal year ending March 31, 2005 was approved. The proposal received 39,258,476 votes for, and 477,511 against ratification. There were 46,797 abstentions and no broker non-votes.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

- 10.1 Employment Agreement dated August 5, 2004, between Mentor Corporation and David Adornetto.
- 10.2 Employment Agreement dated August 5, 2004, between Mentor Corporation and A. Chris Fawzy.
- 10.3 Form of Mentor Corporation Option Agreement.
- 10.4 Written Description of Directors Fees Pursuant to Item 601(b)(10)(iii)(A) of Regulation S-K.
- 10.5 Written Description of Incentive Bonus Plans.
- 10.6 Written Description of Car Allowance Plan
- 31.1 Certification of Principal Executive Officer Pursuant To Section 302 of The Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Principal Financial Officer Pursuant To Section 302 of The Sarbanes-Oxley Act of 2002.
- 32.1 CEO Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 of The Sarbanes-Oxley Act of 2002, filed herewith.
- 32.2 CFO Certification Pursuant To 18 U.S.C. Section 1350, As Adopted Pursuant To Section 906 of The Sarbanes-Oxley Act of 2002, filed herewith.

**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.

**MENTOR CORPORATION**

(Registrant)

Date:	November 5, 2004	By:	<u>/S/JOSHUA H. LEVINE</u> Joshua H. Levine Chief Executive Officer
Date:	November 5, 2004	By:	<u>/S/LOREN L. MCFARLAND</u> Loren L. McFarland Chief Financial Officer

