

MENTOR CORP /MN/  
Form 10-K  
June 14, 2006

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended  
**March 31, 2006**

or

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

Commission File No. 001-31744

**MENTOR CORPORATION**

(Exact name of registrant as specified in its charter)

**Minnesota**  
(State or other jurisdiction of  
incorporation or organization)

**41-0950791**  
(IRS Employer Identification No.)

**201 Mentor Drive, Santa Barbara, California 93111**  
(Address of principal executive offices) (Zip Code)

**(805) 879-6000**  
(Registrant's telephone number, including area code)

Title of Each Class	Name of Each Exchange on Which Registered
<b>Common Shares</b>	<b>New York Stock Exchange</b>
Securities registered pursuant to Section 12(g) of the Act: None	

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

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Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in a definitive proxy or information statement incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

Indicate by check mark whether the Registrant is a shell company (as defined in Exchange Act Rule 12b-2). Yes  No

Based on the closing sale price on the New York Stock Exchange as of the last business day of the Registrant's most recently completed second fiscal quarter (September 30, 2005), the aggregate market value of the Common Shares of the Registrant held by non-affiliates of the Registrant was approximately \$1,616,340,841. For purposes of this calculation, shares held by each executive officer, director and holder of 10% or more of the outstanding shares of the Registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of June 11, 2006, there were approximately 41,326,022 Common Shares outstanding.

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**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement for its Annual Meeting of Shareholders to be held on September 13, 2006 are incorporated by reference into Part III of this Form 10 K.

## MENTOR CORPORATION

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**PART I**

**FORWARD-LOOKING STATEMENTS**

Unless the context indicates otherwise, when we refer to "Mentor," "we," "us," "our," or the "Company" in this Form 10-K, we are referring to Mentor Corporation and its subsidiaries on a consolidated basis. Various statements in this Form 10-K or incorporated by reference into this Form 10-K, in future filings by us with the SEC, in our press releases and in our oral statements made by or with the approval of authorized personnel, constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995.

Forward-looking statements are based on current expectations and are indicated by words or phrases such as "anticipate," "estimate," "expect," "intend," "project," "plan," "believe," "will," "seek," and similar words or phrases and involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of the factors that could affect our financial performance or cause actual results to differ from our estimates in, or underlying, such forward-looking statements are set forth under "Item 1A -Risk Factors" or elsewhere in this Form 10-K. Forward-looking statements include statements regarding, among other things:

- Our anticipated growth strategies;
- Our intention to introduce or seek approval for new products;
- Our ability to continue to meet FDA and other regulatory requirements;
- Our anticipated outcomes of litigation and regulatory reviews; and
- Our ability to replace sources of supply without disruption and regulatory delay
- Our expectation that selling, general and administrative expenses will increase as a result of the adoption of SFAS 123(R) - "Share-Based Payment" which requires all share-based payments be **recognized in the financial statements.**

These forward-looking statements are based largely on our expectations and are subject to a number of risks and uncertainties, many of which are beyond our control. Actual results could differ materially from these forward-looking statements as a result of the facts described in "Item 1A - Risk Factors" or elsewhere including, among others, problems with suppliers, changes in the competitive marketplace, significant product liability or other claims, difficulties with new product development, the introduction of new products by our competitors, changes in the economy, United States Food Drug and Administration ("FDA") delay in approval or rejection of new or existing products, changes in Medicare, Medicaid or third-party reimbursement policies, changes in government regulations, use of hazardous or environmentally sensitive materials, inability to implement new information technology systems, inability to integrate new acquisitions, and other events. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks and uncertainties, we cannot assure you that the forward-looking information contained in this Form 10-K will, in fact, transpire.

**ITEM 1. BUSINESS.**

Mentor Corporation was incorporated in Minnesota in 1969. Our fiscal year ends on March 31, and references to fiscal 2006, fiscal 2005 or fiscal 2004 refer to the years ended March 31, 2006, 2005 or 2004, respectively.

General

We develop, manufacture and market a range of products serving the aesthetic medicine market, including plastic and reconstructive surgery. Aesthetic surgery products include surgically implantable prostheses for plastic and reconstructive surgery, capital equipment and consumables used for soft tissue aspiration or body contouring (liposuction), and facial aesthetics products.



Historically we have had three reportable segments: aesthetic and general surgery, surgical urology, and clinical and consumer healthcare. In October 2005, we announced a strategy to increase our focus on aesthetic medicine, and as a result we pursued strategic alternatives for our surgical urology and clinical and consumer healthcare businesses. On March 27, 2006, we announced that we received a binding offer from Coloplast A/S ("Coloplast") regarding the sale of these businesses. On May 17, 2006, we entered into a definitive purchase agreement for the sale of our surgical urology and clinical and consumer healthcare business segments (collectively, the "Urology Business") to Coloplast for total consideration of \$463,225,000, of which \$456,137,500 would be in cash and \$7,087,500 in non-cash consideration, and on June 2, 2006 we completed this sale to Coloplast.

In connection with the sale, we have entered into a Transition Services Agreement ("TSA") and various supply agreements. Pursuant to the TSA, we will provide to Coloplast, and Coloplast will provide to us, services including accounting, regulatory, clinical, information technology, customer support, and use of facilities in exchange for specified fees. Under the supply agreements we will supply various products, including silicone gel-filled testicular implants to Coloplast, and Coloplast will supply to us various components for the manufacture of our breast implants. It is anticipated that services provided under the TSA will continue for a period of up to twelve months, and the supply agreements range from a period of 6-36 months. As a result of the sale, the operations of our surgical urology and clinical and consumer healthcare segments have been classified as discontinued operations in our consolidated balances sheets, consolidated statements of income, consolidated statement of cash flows and the notes to the consolidated financial statements included herein for all periods presented. The following information relates to our continuing operations in the aesthetic medicine business and does not discuss (other than briefly) the business of our discontinued segments. For further discussion related to discontinued operations, see "Item 7, Management Discussion and Analysis of Financial Condition and Results of Operations" and Note T of the notes to consolidated financial statements of this Form 10-K.

#### Recent Events

On April 3, 2006, we submitted a pre-market approval application to the U.S. Food and Drug Administration ("FDA") for our Contour Profile® silicone gel-filled breast implant products ("CPG™"). The FDA has initiated its review of our application with the exception of our clinical module, which based on discussions with FDA will require additional information, and we are in the process of collecting that information.

On March 20, 2006, we signed a non-binding letter of intent with Niadyne, Inc. to distribute Niadyne's innovative NIA 24™ line of science-based cosmeceutical products used to improve and restore the healthy appearance of the skin. We believe that these cosmeceutical products will complement our facial aesthetics business.

On February 6, 2006, we announced that, with respect to our Puragen Plus™ program in the U.S., we had identified potential issues that required further evaluation of our clinical study data and would result in a delay to our PMA submission timeline. We performed this evaluation, and we concurrently reviewed some of our critical production processes. Based on the results of this evaluation we have developed a plan to move forward with our Puragen Plus™ PMA process, and are targeting to submit the first module to FDA in late summer or early fall this year, and to complete the submission in the spring of 2007.

On July 28, 2005, we received an "approvable letter" with conditions from the FDA on our pre-market approval application for our MemoryGel™ round silicone gel-filled breast implants. The approvable letter stipulates a number of conditions which we must satisfy in order to receive FDA approval to market and sell silicone gel-filled breast implants in the United States. These conditions were generally consistent with those conditions that the advisory panel, composed of outside experts selected by the FDA, had recommended in their April 2005 review of our PMA application. We remain in discussion with the FDA regarding the conditions for approval of our MemoryGel™ breast implant pre-market approval application, including discussions regarding post-market patient monitoring and data collection. We expect to incur additional expenses in connection with such post-market patient monitoring and data collection, which could be substantial. In addition, we cannot guarantee that the FDA will provide final approval, nor can we determine when the FDA's decision regarding approval will be made.

Principal Products and Markets

Our aesthetic medicine products fall into three general categories: breast implants, body contouring, and other aesthetics which includes facial aesthetics products. Net sales for each of these product categories and the percentage contributions of such net sales to total net sales are as follows:

(in thousands)	2006		Year Ended March 31, 2005		2004	
	Amount	%	Amount	%	Amount	%
Breast implants	\$ 233,189	87.0%	\$ 217,420	86.4%	\$ 194,052	88.8%
Body contouring	17,782	6.6%	18,609	7.4%	15,276	7.0%
Other aesthetics, including non-surgical facial products	17,301	6.4%	15,697	6.2%	9,109	4.2%
Total	\$ 268,272	100.0%	\$ 251,726	100.0%	\$ 218,437	100.0%

We develop, produce, and market a broad line of breast implants, including saline-filled implants and silicone gel-filled (MemoryGel™) implants. Our breast implants consist of a silicone elastomer shell that is either filled during surgery with a saline solution or pre-filled during the manufacturing process with silicone gel. Our MemoryGel™ products come in varying degrees of cohesiveness. Additionally, all of our implants have either a smooth or textured surface and are provided in a variety of sizes and shapes to meet the varying preferences of patients and surgeons.

Mammary prostheses have applications in both cosmetic and reconstructive plastic surgery procedures. These prostheses are used in augmentation procedures to enhance breast size and shape, correct breast asymmetries and help restore fullness after breast feeding. During reconstruction procedures, mammary prostheses are utilized as a surgical solution to create a breast mound following a mastectomy. Breast reconstruction is a surgical option for many women following a mastectomy, either at the time of surgery or a later date.

We carry a full line of breast reconstruction products including the Contour Profile Tissue Expander (CPX®) family of breast expanders. These expansion products, used in the first-stage of a two-stage breast reconstruction, create a pocket that will ultimately hold the breast implant that is placed in a subsequent second-stage operation. All of the CPX devices utilize our proprietary BufferZone™ self-sealing technology and Centerscope™ injection port locators. We also are the industry leader for single-stage breast reconstruction procedures, with our line of smooth and textured Becker implants, which are designed to be used as both an expander and a permanent implant.

We offer a line of extremity tissue expanders. Extremity tissue expansion involves the process of growing additional tissue for reconstruction and skin graft procedures. Some of the major applications of extremity tissue expansion include the correction of disfigurements such as burns, large scars and congenital deformities.

With respect to body contouring, we market through our subsidiary, Byron Medical, Inc., a complete line of liposuction products and disposable supplies.



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In fiscal 2005, we established two new business lines in the aesthetics arena, which we categorize under "other aesthetics": Mentor Solutions and Facial Aesthetics. We had previously acquired a company called Inform Solutions and during fiscal 2005 combined it into a new business called Mentor Solutions. The Mentor Solutions group offers software, consulting and business management tools to help plastic surgeons grow their business.

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In the Facial Aesthetics area, we launched our new dermal filler product, Puragen™, in a variety of international markets in May 2005 and have received additional international approvals throughout 2005. Puragen™ is our proprietary non-animal based, hyaluronic acid dermal filler. In February 2006, we announced that, with respect to our Puragen Plus™ program in the U.S., we had identified potential issues that required further evaluation of our clinical study data and would result in a delay to our PMA submission timeline. We performed this evaluation, and we concurrently reviewed some of our critical production processes. Based on the results of this evaluation we have developed a plan to move forward with our Puragen Plus™ PMA process, and are targeting to submit the first module to FDA in late summer or early fall this year, and to complete the submission in the spring of 2007.

We are developing a next-generation botulinum toxin type A product based on proprietary technology that yields a formulation designed to be purer than other commercially available botulinum toxin products. During fiscal 2005, we initiated the United States phase 1 dose escalation study for cosmetic indications and during fiscal 2006 we initiated the United States phase 2 dose-finding study for cosmetic indications, and all patients in the Phase 2 study have been enrolled. In addition, in early fiscal 2007 we initiated the United States phase 1 dose-escalation study focused on the treatment of adult-onset spasmodic torticollis/cervical dystonia.

In March 2006, we signed a non-binding letter of intent with Niadyne Inc., to distribute Niadyne's innovative NIA 24™ line of science-based cosmeceutical products used to improve and restore the healthy appearance of the skin.

### Sales and Marketing

We employ a domestic sales force for our aesthetic surgery and body contouring product lines. The sales force provides product information and specific data support and related services to physicians, nurses and other health care professionals. We promote our products through participation in and sponsorship of medical conferences and educational seminars, radio, newspaper, specialized websites, journal advertising, direct mail programs, and a variety of marketing support programs. In fiscal 2005, we launched the first primetime advertising campaign in the industry for our saline breast implant products. We ran commercials on ABC's *Extreme Makeover* program for the 2004/05 season while at the same time launching our *Mentor4me.com* patient education program designed to help educate interested women about breast augmentation surgery and help them locate surgeons. During fiscal 2005 and into the beginning of fiscal 2006 these commercials also ran during ABC's Daytime programming and ABC's *Desperate Housewives* program. In addition, we contribute to organizations that provide counseling and education for persons suffering from certain conditions, and we provide patient education materials for most of our products to physicians for use with their patients.

### International Operations

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, Benelux, Australia, Spain, Portugal and Italy, as well as through independent distributors in other countries. Total foreign net sales, which are made through distributors and direct international sales offices, for continuing operations were \$75.5 million, \$65.2 million, and \$55.0 million in fiscal 2006, 2005 and 2004, respectively. Other than sales made through our international sales offices, which are denominated in the local currency of the sales office, export sales are made in United States dollars.

In addition, we manufacture mammary implants in The Netherlands and facial products in the United Kingdom. Total long-lived assets, excluding those related to discontinued operations, located in foreign countries were \$29.5 million, \$30.5 million, and \$30.9 million as of March 31, 2006, 2005 and 2004, respectively.

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For additional information regarding our international operations, see "Note U - Business Segment Information" of the "Notes to the Consolidated Financial Statements."

### Competition

We believe we are one of the leading suppliers of cosmetic and reconstructive surgery products. This belief is based upon information developed internally, public information sources, and information from independent research studies of market share.

In the domestic breast implant market, we compete primarily with one other company, Allergan Inc., which acquired Inamed Corporation in March 2006. The primary competitive factors in this market currently are product performance and quality, range of styles and sizes, proprietary design, warranty programs, customer service and, in certain instances, price. Outside the U.S., we compete with Allergan and various smaller competitors.

### Government Regulations

#### *General*

As a manufacturer of medical devices and developer of biologic products, our manufacturing processes and facilities are subject to continuing review by the FDA and various state and international agencies ("Agencies"). These Agencies inspect our processes and facilities from time to time to determine whether we are in compliance with various regulations relating to manufacturing practices and other requirements. These Agencies have the power to prevent or limit further marketing of products based upon the results of these inspections. These regulations depend heavily on administrative interpretation. There can be no assurance that future interpretations made by these Agencies will not adversely affect us. Failure to comply with these Agencies' regulatory requirements may result in enforcement action by these Agencies, including product recalls, suspension or revocation of product approval, seizure of product to prevent distribution, imposition of injunctions prohibiting product manufacture or distribution, and civil or criminal penalties.

Advertising and promotion of medical devices and biologic products are regulated by the FDA and the Federal Trade Commission ("FTC") in the U.S. and by analogous agencies internationally. A determination that we are in violation of regulatory requirements governing promotional activities could lead to imposition of various penalties, including warning letters, product recalls, injunctive relief, and civil or criminal penalties.

Products and materials manufactured internationally may come under Homeland Security statutes from time to time and could be considered for restricted entry into the United States by FDA and U.S. Customs. The restricted entry of such products and materials could affect the manufacturing and sale of product domestically and internationally. Our products may also be subject to export control regulations.

#### *Regulation of Medical Devices*

Under the Federal Food, Drug, and Cosmetic Act ("FDCA") as amended, the FDA has the authority to adopt regulations that: (i) set standards and general controls for medical devices; (ii) require demonstration of safety and effectiveness or other forms of data support prior to marketing devices which the FDA requires pre-market approval or clearance; (iii) require test data to be submitted to the FDA prior to evaluation in

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humans; (iv) permit detailed inspections of device manufacturing facilities; (v) establish Good Manufacturing Practices ("GMPs"), now referred to as the Quality System Regulation ("QSR") that must be followed in device and biologic manufacture; (vi) require reporting of certain adverse events, device malfunctions, and other post-market information to the FDA; and (vii) prohibit device or biologic exports that do not meet certain requirements. The FDA also regulates promotional activities by device companies. Essentially all of our products currently marketed are medical devices and are therefore subject to FDA regulation in the U.S. and analogous foreign agencies for the international countries to which we export our products. We expect the products, such as Puragen Plus<sup>TM</sup>, that we are developing to also be subject to FDA regulation as either biologics or medical devices.

The FDCA established complex procedures for FDA regulation of devices. Devices are placed in three classes: Class I (general controls to preclude misbranding or adulteration, compliance with labeling and other requirements), Class II (special controls and FDA clearance in addition to general controls), and Class III (a pre-market approval application ("PMA") before commercial marketing). Class III devices are the most extensively regulated. Class III devices require each manufacturer to submit to the FDA a PMA that includes information demonstrating the safety and effectiveness of the device. The majority of our aesthetic surgery products are in Class III.

In 1991, we submitted a PMA for our silicone gel-filled mammary prostheses to the FDA. In 1992, the FDA's outside advisory panel on aesthetic surgery products indicated that although there was insufficient data to establish with reasonable certainty that silicone gel implants were safe and effective, there was a public health need for these types of implants. Adopting the recommendations of the panel, the FDA denied the pending applications for the use of silicone gel-filled breast implants for augmentation, but provided for the continued availability of the implants for reconstruction and revision purposes on the basis of a public health need. Since 1992, women have been required to enroll in a clinical program for future follow-up in order to receive gel-filled implants for reconstruction. Patients are required to sign an informed consent form and physicians must certify that saline implants are not a satisfactory alternative. We continue to ship these products under the terms of this clinical program, and these shipment activities require device tracking and documentation support to ensure compliance and accountability.

In 1994, the FDA published proposed guidelines for the PMA applicable to our saline-filled breast implants. We submitted all the required data for our saline implants, and the FDA approved our application on May 10, 2000. In conjunction with its review of the data, the FDA inspected our manufacturing facility in Irving, Texas and indicated the facility was in substantial compliance with the applicable regulations.

In December 2003, we completed the submission of our PMA application for our MemoryGel™ round silicone gel-filled breast implants to the FDA for breast augmentation, reconstruction and revision. The FDA indicated that our PMA "is sufficiently complete to permit a substantive review and is, therefore, suitable for filing." On January 8, 2004, the FDA released a "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. In August 2004, we amended our PMA based on January 2004 revised (new) FDA draft guidance and responded to other issues raised by the FDA. On April 11-13, 2005, an advisory panel composed of outside experts selected by the FDA met to consider questions presented to it by the FDA regarding our and our competitor's PMA submissions and to make a recommendation to the FDA regarding whether the PMA applications should be approved. In a majority 7-2 vote, the panel recommended approval of our PMA submission to the FDA, with conditions. On July 28, 2005, we received an "approvable letter" with conditions from the FDA on our PMA application. The approvable letter stipulates a number of conditions which we must satisfy in order to receive FDA approval to market and sell silicone gel-filled breast implants in the United States. These conditions were generally consistent with those conditions that the advisory panel had recommended. We remain in discussion with the FDA regarding the conditions for approval of our MemoryGel™ breast implant PMA application, including discussions regarding post-market patient monitoring and data collection. We expect to incur additional expenses in connection with such post-market patient monitoring and data collection, which could be substantial. We cannot guarantee that the FDA will provide final approval, nor can we determine when the FDA's decision regarding approval will be made.

On April 3, 2006, we submitted a pre-market approval application to the U.S. Food and Drug Administration ("FDA") for our Contour Profile® silicone gel-filled breast implant products ("CPG™"). The FDA has initiated its review of our application with the exception of our clinical module, which based on discussions with FDA will require additional information, and we are in the process of collecting that information.

We also have two pending applications for Medical Device Licenses in Canada for our silicone gel-filled breast implants. An expert advisory panel was convened by the Canadian government on March 22, 2005 to review our pending application for Medical Device Licenses. Health Canada held a public forum on these devices September 29, 2005. We cannot predict the timing or outcome of the review and forum or determine when or if Health Canada will approve our product applications.

*Biologics*

Certain other products being developed by us are regulated by the FDA as biologics under the Public Health Service Act requiring pre-marketing approval, and are subject to regulations and requirements on preclinical and clinical testing, manufacture, labeling, quality control, storage, advertising, promotion, marketing, distribution, and export. Prior to commercial sale of a biologic, a Biologics License Application ("BLA") that includes results from required, well-controlled clinical trials to establish the safety and effectiveness for the product's intended use, and specified manufacturing information, must be submitted to and approved by the FDA. FDA inspection of the manufacturing facility during review of the BLA is required to ensure that manufacturing processes conform to FDA-mandated GMPs. Continued compliance with GMPs is required after product approval, and post-approval changes in manufacturing processes or facilities, product labeling, or other areas require FDA review and approval. We are also subject to regulation by the U.S. Department of Health and Human Services, Centers for Disease Control, due to the nature of the biological agent used to manufacture our botulinum toxin product, *Clostridium botulinum* type A, which is still in the development phase. Failure to comply with the regulations and requirements of these various agencies could affect our ability to manufacture products and may have a significant negative future impact on sales and results of operations.

We have incurred, and will continue to incur, substantial costs relating to laboratory and clinical testing of new and existing products and the preparation and filing of documents required by the FDA for product approval. The process of obtaining marketing clearance and approvals from the FDA can be time consuming and expensive, and there is no assurance that such clearances or approvals will be granted. We also may encounter delays in bringing new products to market as a result of being required by the FDA to conduct and document additional investigations of product safety and effectiveness, which may adversely affect our ability to commercialize additional products or additional applications for existing products.

*Additional Regulations*

As a manufacturer of medical devices and biologics, our manufacturing processes and facilities are subject to regulation and review by international regulatory agencies for products sold internationally.

A medical device may only be marketed in the European Union ("EU") if it complies with the Medical Devices Directive (93/42/EEC) ("MDD") and bears the CE mark as evidence of that compliance. To achieve this, the medical devices in question must meet the "essential requirements" defined under the MDD relating to safety and performance, and we as manufacturer of the devices must undergo verification of our regulatory compliance by a third party standards certification provider, known as a "Notified Body". We have obtained CE marking for our products sold in the EU by demonstrating compliance with the MDD and ISO13485 2003 international quality system standards. Medical device laws and regulations are also in effect in some of the other countries to which we export our products. These range from comprehensive device approval requirements for some or all of our medical device products, to requests for product data or certifications. Failure to comply with these international regulatory standards and requirements, and to changes in the international quality system standards, could affect our ability to market and sell products in these markets and may have a significant negative impact on sales and results of operations.

Additional products in the area of biologics are being developed, which will be regulated as medicinal products in the EU and as such will require a marketing authorization before they can be introduced into the market. There are two routes by which this can be achieved: the centralized procedure whereby an approval granted by the European Commission permits the supply of the product in question throughout the EU, or the Mutual Recognition Procedure ("MRP") where a marketing authorization granted by one national authority is recognized by the authorities of the other member states in which we intend to supply the products. The centralized procedure is compulsory for biotechnology products and is optional for certain high-technology products. All such products which are not authorized by the centralized route must be authorized by the MRP unless the product is designed for a single EU country, in which case a national application can be made. In each case, the application must contain full details of the product and the research that has been carried out to establish its efficacy, safety and quality.





Our present and future business has been and will continue to be subject to various other laws and regulations, including state and local laws relating to such matters as safe working conditions and disposal of potentially hazardous substances. We may incur significant costs in complying with such laws and regulations now, or in the future, and any failure to comply may have a material adverse impact on our business.

#### *Environmental Regulation*

We are subject to federal, state, local and foreign environmental laws and regulations. Our manufacturing and research and development activities involve the controlled use of potentially hazardous materials, chemicals and biological materials, which require compliance with various laws and regulations regarding the use, storage, and disposal of such materials. We believe that our operations comply in all material respects with applicable environmental laws and regulations in each country where we have a business presence. Although we continue to make expenditures for environmental protection, we do not anticipate any additional significant expenditures, in complying with such laws and regulations, that would have a material impact on our earnings or competitive position. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse effect on our financial position. We cannot provide any assurance, however, that environmental claims will not develop in the future including claims for indemnification, relating to our operations or properties owned or operated by us, or those properties previously owned by us and divested as part of the transaction with Coloplast, nor can we predict whether any such claims, if they were to develop, would require significant expenditures on our part. There can be no assurance that violations of environmental health and safety laws will not occur in the future as a result of the inability to obtain permits, human error, equipment failure or other causes, which could result in fines and penalties or adversely affect our operating results and harm our business. In addition, environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations.

We are subject to regulation by the United States Environmental Protection Agency and other state and local environmental agencies in each of our domestic manufacturing facilities. For example, in Texas, we are subject to regulation by the local Air Pollution Control District as a result of some of the chemicals used in our manufacturing processes. Failure to comply with the regulations and requirements of these various agencies could affect our ability to manufacture our existing products or could result in a claim for indemnification and may have a significant negative impact on sales and results of operations, including discontinued operations.

#### Medicare, Medicaid and Third-Party Reimbursement

Health care providers that purchase medical devices, such as our products, generally rely on third-party payors, including the Medicare and Medicaid programs and private payors, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the products. In the United States, our aesthetics products are sold principally to hospitals, surgery centers and surgeons. We invoice our customers and they remit directly to us. In some cases, the patient and the procedure may be eligible for reimbursement by third-party payors, including Medicare, Medicaid and other similar programs, but this coverage is invisible to us on a case-by-case basis. However, we are aware that some of our customers are being reimbursed, in full or in part, for our products or for procedures that utilize our products. The majority of procedures that utilize our products are not reimbursable by these third-party payors. Nevertheless, reimbursement can be a significant market factor when the product cost represents a major portion of the total procedure cost and the reimbursement for that procedure (or alternative procedures) is changing, or influencing treatment decisions. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payors. The manner in which reimbursement is sought and obtained for any of our products varies based upon the type of payor involved and the setting in which the product is furnished and utilized by patients.



Payments from Medicare, Medicaid and other third party payors are subject to legislative and regulatory changes and are susceptible to budgetary pressures. Some of our customers' revenues and ability to purchase our products and services is therefore subject to the effect of those changes and to possible reductions in coverage or payment rates by third-party payors. Any changes in the health care regulatory, payment or enforcement landscape relative to our customers' health care services may negatively affect our operations and revenues. Discussed below are certain factors which could have a negative impact on our future operations and financial condition. It is difficult to predict the effect of these factors on our operations; however, the effect could be negative and material.

#### *Medicare Overview*

Medicare is a federal program administered by the Centers for Medicare and Medicaid Services ("CMS"), formerly known as HCFA, through fiscal intermediaries and carriers. Available to individuals age 65 or over, and certain other classes of individuals, the Medicare program provides, among other things, health care benefits that cover, within prescribed limits, the major costs of most medically necessary care for such individuals, subject to certain deductibles and co-payments. There are three components to the Medicare program relevant to our business: Part A, which covers inpatient services, home health care and hospice care; Part B which covers physician services, other health care professional services and outpatient services; and Part C or Medicare Advantage, which is a program for managed care plans.

The Medicare program has established guidelines for the coverage and reimbursement of certain equipment, supplies and services. In general, in order to be reimbursed by Medicare, a health care item or service furnished to a Medicare beneficiary must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part. The methodology for determining (1) the coverage status of our products; and (2) the amount of Medicare reimbursement for our products, varies based upon, among other factors, the setting in which a Medicare beneficiary received health care items and services. Any changes in federal legislation, regulations and policy affecting Medicare coverage and reimbursement relative to our products could have a material effect on our performance.

A portion of our revenue is derived from our customers who operate inpatient hospital facilities. Acute care hospitals are generally reimbursed by Medicare for inpatient operating costs based upon prospectively determined rates. Under the Prospective Payment System, or PPS, acute care hospitals receive a predetermined payment rate based upon the Diagnosis-Related Group, or DRG, into which each Medicare beneficiary stay is assigned, regardless of the actual cost of the services provided. Certain additional or "outlier" payments may be made to a hospital for cases involving unusually high costs. Accordingly, acute care hospitals generally do not receive direct Medicare reimbursement under PPS for the distinct costs incurred in purchasing our products. Rather, reimbursement for these costs is deemed to be included within the DRG-based payments made to hospitals for the services furnished to Medicare-eligible inpatients in which our products are utilized. Because PPS payments are based on predetermined rates and are often less than a hospital's actual costs in furnishing care, acute care hospitals have incentives to lower their inpatient operating costs by utilizing equipment, devices and supplies, including those sold by us, that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. Our product revenue could be affected negatively if acute care hospitals discontinue product use due to insufficient reimbursement, or if other treatment options are perceived to be more profitable.

#### *Medicare - Outpatient Hospital Setting*

CMS implemented the hospital Outpatient Prospective Payment System, or OPPTS, effective July 1, 2000. OPPTS is the current payment methodology for hospital outpatient services, among others. Services paid under the OPPTS are classified into groups called Ambulatory Payment Classifications, or APC. Services grouped within each APC are similar clinically and in terms of the resources they require. A payment rate is established for each APC through the application of a conversion factor that CMS updates on an annual basis. OPPTS may cause providers of outpatient services with costs above the payment rate to incur losses on such services provided to Medicare beneficiaries.



The Balanced Budget Refinement Act of 1999 provides for temporary financial relief from the effects of OPSS through the payment of additional outlier payments and transitional pass-through payments to outpatient providers reimbursed through OPSS who qualify for such assistance. Transitional pass-through payments are required for new or innovative medical devices, drugs, and biological agents. The purpose of transitional pass-through payments is to allow for adequate payment of new and innovative technology until there is enough data to incorporate cost for these items into the base APC group. The qualification of a device for transitional pass-through payments is temporary.

Annually CMS proposes, and after consideration of public comment, implements changes to OPSS and payment rates for the following calendar year. The OPSS methodology determines the amount hospitals will be reimbursed for procedures performed on an outpatient basis and determines the profitability of certain procedures for the hospital and may impact hospital purchasing decisions.

We cannot predict the final effect that any change in OPSS regulations, including future annual updates, will have on our customers or our revenues. Any such effect, however, could be negative if APC groupings become less advantageous, reimbursement allowables decline, or if the OPSS is modified in any other manner detrimental to our business.

#### *Medicaid*

The Medicaid program is a cooperative federal/state program that provides medical assistance benefits to qualifying low income and medically needy persons. State participation in Medicaid is optional and each state is given discretion in developing and administering its own Medicaid program, subject to certain federal requirements pertaining to payment levels, eligibility criteria and minimum categories of services. The coverage, method and level of reimbursement varies from state to state and is subject to each state's budget restraints. Changes to the coverage, method or level of reimbursement for our products may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

#### *Private Payors*

Many third-party private payors, including indemnity insurers, employer group health insurance programs and managed care plans, presently provide coverage for the purchase of our products. The scope of coverage and payment policies varies among third-party private payors. Furthermore, many such payors are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Cost containment pressures have led to an increased emphasis on the use of cost-effective technologies and products by health care providers. Future changes in reimbursement methods and cost control strategies may limit or discontinue reimbursement for our products and could have a negative effect on revenues and results of operations.

#### *Health Care Fraud and Abuse Laws and Regulations*

The federal government has made a policy decision to significantly increase the financial resources allocated to enforcing the health care fraud and abuse laws. Private insurers and various state enforcement agencies also have increased their level of scrutiny of health care claims and arrangements in an effort to identify and prosecute fraudulent and abusive practices in the health care industry. We monitor compliance with federal and state laws and regulations applicable to the health care industry in order to minimize the likelihood that we would engage in conduct or enter into contracts that could be deemed to be in violation of the fraud and abuse laws. The health care fraud and abuse laws to which we are

subject include the following, among others:

*Federal and State Anti-Kickback Laws and Safe Harbor Provisions*

The federal anti-kickback laws make it a felony to knowingly and willfully offer, pay, solicit or receive any form of remuneration in exchange for referring, recommending, arranging, purchasing, leasing or ordering items or services covered by a federal health care program, including Medicare or Medicaid, subject to various "safe harbor" provisions. The anti-kickback prohibitions apply regardless of whether the remuneration is provided directly or indirectly, in cash or in kind, and various state laws have similar prohibitions that are sometimes broader in nature. Interpretations of the law have been very broad. Under current law, courts and federal regulatory authorities have stated that the federal law is violated if even one purpose (as opposed to the sole or primary purpose) of the arrangement is to induce referrals. A violation of the federal statute is a felony and could result in civil and administrative penalties, including exclusion from the Medicare or Medicaid program, even if no criminal prosecution is initiated.

The Department of Health and Human Services has issued regulations from time to time setting forth safe harbors, which would guarantee protection of certain limited types of arrangements from prosecution under the statute if all elements of a particular safe harbor are met. However, failure to fall within a safe harbor or within each element of a particular safe harbor does not mean that an arrangement is *per se* in violation of the federal anti-kickback laws. As the comments to the safe harbors indicate, the purpose of the safe harbors is not to describe all illegal conduct, but to set forth standards for certain non-violative arrangements. If an arrangement violates the federal anti-kickback laws and full compliance with a safe harbor cannot be achieved, we risk greater scrutiny by the Office of the Inspector General, ("OIG"), and, potentially, civil and/or criminal sanctions. We believe our arrangements are in compliance with the federal anti-kickback laws, and analogous state laws; however, regulatory or enforcement authorities may take a contrary position, and we cannot assure that these laws will ultimately be interpreted in a manner consistent with our practices.

*Federal False Claims Act*

We are subject to state and federal laws that govern the submission of claims for reimbursement. The federal False Claims Act imposes civil liability on individuals or entities that submit (or "cause" to be submitted) false or fraudulent claims to the government for payment. Violations of the False Claims Act may result in civil monetary penalties for each false claim submitted treble damages and exclusion from the Medicare and Medicaid programs. In addition, we could be subject to criminal penalties under a variety of federal statutes to the extent that we knowingly violate legal requirements under federal health programs or otherwise present (or cause to be presented) false or fraudulent claims or documentation to the government. In addition, the OIG may impose extensive and costly corporate integrity requirements upon a health industry participant that is the subject of a false claims judgment or settlement. These requirements may include the creation of a formal compliance program, the appointment of a government monitor, and the imposition of annual reporting requirements and audits conducted by an independent review organization to monitor compliance with the terms of any such compliance program, as well as the relevant laws and regulations.

The False Claims Act also allows a private individual to bring a "qui tam" suit on behalf of the government for violations of the False Claims Act, and if successful, the "qui tam" individual shares in the government's recovery. A qui tam suit may be brought, with only a few exceptions, by any private citizen who has material information of a false claim that has not yet been previously disclosed. Recently, the number of qui tam suits brought in the health care industry has increased dramatically. In addition, several states have enacted laws modeled after the False Claims Act.

Under the Deficit Reduction Act of 2005, Congress encouraged states to enact state false claims acts that are similar to the federal False Claims Act, including "qui tam" provisions. As states enact such laws, the risk of being subject to a state false claims action will increase.

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Additionally, the U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay, authorize to payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Our present and future business has been and will continue to be subject to various other laws, rules, and/or regulations.



### Product Development

We are focused on the development of new products and improvements to existing products, as well as obtaining FDA approval of certain products and processes, and we maintain the highest quality standards of existing products. During fiscal years 2006, 2005 and 2004, we spent a total of \$29.0 million, \$25.2 million and \$ 21.1 million, respectively, for research and development primarily in support of our silicone gel breast implant regulatory submissions in the United States and Canada, laboratory testing and clinical studies for our hyaluronic acid-based dermal filler Puragen™ and our botulinum toxin products.

### Patents and Licenses

It is our policy to protect our intellectual property rights relating to our products whenever possible and appropriate. Our patents and licenses relating to continuing operations include those relating to tissue expanders, a combination breast implant and tissue expander (Becker implant), and body contouring (liposuction) equipment. We believe that although our patents and licenses are material in their totality, no single patent or license is material to our business as a whole.

In those instances where we have acquired technology from third parties, we have sought to obtain rights of ownership to the technology through the acquisition of underlying patents or licenses. While we believe design, development, regulatory and marketing aspects of the medical device business represent the principal barriers to entry into such business, we also recognize that our patents and license rights may make it more difficult for our competitors to market products similar to those we produce. We can give no assurance that our patent rights, whether issued, subject to license, or in process, will not be circumvented, terminated, or invalidated. Further, there are numerous existing and pending patents on medical products and biomaterials. We can give no assurance that our current, former or planned products do not or will not infringe such rights or that others will not claim such infringement or that we will be able to prevent competitors from challenging our patents or entering markets currently served by us.

### Raw Material Supply and Single Source Suppliers

We obtain certain raw materials and components for a number of our products from single source suppliers, including our implant quality silicone elastomers and gel materials for mammary prostheses and certain components used for those prostheses. We believe our sources of supply could be replaced if necessary, but it is possible that the process of qualifying new materials and/or vendors for certain raw materials and components could cause an interruption in our ability to manufacture our products and potentially have a material negative impact on sales. No significant interruptions to raw material supplies occurred during fiscal 2006.

Our saline-filled mammary implants and other products are available for sale in the United States under FDA approvals and/or clearances. Gel-filled mammary implants are only available in the United States as part of the adjunct clinical study. A change in raw material, components or suppliers for products may require a new FDA submission, and subsequent review and approval. There is no assurance that such a submission would be approved without delay, or at all. Any delay or failure to obtain approval may have a significant adverse impact on our sales and results of operations.

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In connection with the sale of our Urology Business to Coloplast, we have entered into a supply agreement with Coloplast for certain components of our breast implant products. For the short-term, Coloplast would be our sole source for these components, and if we were unable to obtain this supply, our business would be harmed. We may determine that we do not want to continue to purchase products from Coloplast or Coloplast may be unable to meet our needs in a timely manner, either of which may disrupt our business during the period we negotiate a supply agreement with, and qualify the manufacturing process of, a third party or begin production of the components ourselves.

### Seasonality

Our quarterly results reflect slight seasonality, as the second fiscal quarter ending September 30 tends to have the lowest revenue of all of the quarters. This is primarily due to lower levels of sales of breast implants for augmentation, an elective procedure, as surgeons and patients tend to take vacation, particularly in Europe, during this quarter.

### Working Capital

We maintain normal industry levels of inventory for our business. This includes significant consignment inventories of our aesthetics products to aid the surgeon in correctly sizing an implant to meet patient needs and to reduce the rate of returns of products that are purchased in order to facilitate sizing options. Inventories are managed to levels consistent with high levels of customer service. Additionally, new product introductions require inventory build-ups to ensure success.

Our accounts receivable credit terms are consistent with normal industry practices in the markets that we sell our products. Aesthetic surgery product return policies allow for product returns for full or partial credit for up to six months. It is common practice to order additional quantities and sizes to facilitate correct sizing to meet patient needs. Consequently, product return rates are high but are considered to be consistent with the industry rates. See "Application of Critical Accounting Policies - Revenue Recognition" of "Management's Discussion and Analysis of Financial Condition and Results of Operations."

### Employees

As of March 31, 2006, we employed approximately 950 people in our continuing operations, of whom 490 were in manufacturing, 202 in sales and marketing, 82 in research and development and 176 in finance and administration. Including the discontinued operations (surgical urology and clinical and consumer healthcare segments), at March 31, 2006, we employed a total of approximately 2,040 people, of whom 1,075 were in manufacturing, 525 in sales and marketing, 123 in research and development and 317 in finance and administration. We have never had a work stoppage due to labor difficulties, and we consider our relations with our employees to be satisfactory.

### Discontinued Operations

On May 17, 2006, we entered into a definitive Purchase Agreement with Coloplast for the sale of our surgical urology and clinical and consumer healthcare business segments for total consideration of \$463,225,000, of which \$456,137,500 is in cash and \$7,087,500 in non-cash consideration consisting of the value of certain foreign tax credits that Mentor expects to realize arising from the transaction prior to the close. On June 2, 2006, we completed this sale to Coloplast. The Purchase Agreement provides, among other things, that we will not enter into or engage in a business that competes with the business as sold, on a worldwide basis, for a period of seven years following the closing. This restriction on competition does not apply to (i) development, manufacture or sale of any oral pharmaceuticals or any product or treatments involving dermal fillers or other bulking agents or toxins, including botulinum toxins, or (ii) any businesses acquired and operated by us or our affiliates for so long as such competing businesses generate less than \$5 million in aggregate annual revenues. These restrictions on competition terminate upon a change in control of Mentor. On June 1, 2006, our Porges SAS subsidiary sold certain intellectual property to Coloplast for \$52 million which is included in the total consideration. In connection with the sale, we entered into a Transition Services Agreement ("TSA") and various supply agreements. Pursuant to the TSA, in exchange for specified fees, we will provide to Coloplast, and Coloplast will provide to us, services including accounting, regulatory, clinical, information technology, customer support and use of facilities. Under the supply agreements, we will supply various products, including silicone gel-filled testicular implants to Coloplast and Coloplast will supply to us various component products to us. Coloplast will reimburse us for certain fees and expenses related to the services we perform under the TSA. Certain

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of these services that we will provide are expected to extend for a period of up to 12 months, and the supply agreements range from a period of 6 - 36 months. On June 2, 2006, we also completed the sale of our intellectual property, raw materials and tangible assets for the production of silicone male external catheters relating to our catheter production facility in Anoka, Minnesota and our inventory of such catheters to Rochester Medical Corporation, for an aggregate purchase price of approximately \$1.6 million.

Our former surgical urology segment included 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 former clinical and consumer healthcare products included catheters and other products for the management of urinary incontinence and retention. The surgical urology and clinical and consumer healthcare segments sold to Coloplast contributed approximately 47% of our pre-divestiture consolidated net sales and approximately 27% of our operating profit in fiscal 2006. Net assets held for sale comprised approximately 51% of total pre-divestiture net assets in fiscal 2006.

Executive Officers of the Registrant

Our executive officers as of June 11, 2006 are listed below, followed by brief accounts of their business experience and certain pertinent information as of that date.

Name	Age	Position
Joshua H. Levine	47	President and Chief Executive Officer
Loren L. McFarland	47	Vice President, Chief Financial Officer and Treasurer
David J. Adornetto	44	Vice President, Operations
Kathleen M. Beauchamp	41	Vice President, Sales and Marketing
A. Christopher Fawzy	36	Vice President, General Counsel and Secretary

**Joshua H. Levine** has served as the President and Chief Executive Officer and a director since May 2004. He was President and Chief Operating Officer from December 2003 to May 2004, Senior Vice President, Global Sales and Marketing from June 2002 to December 2003, Vice President Domestic Sales and Marketing for Aesthetic Products from September 2000 to June 2002, assuming global responsibilities for all of aesthetic sales and marketing activities in November 2001. He joined us as Vice President, Sales, Aesthetic Products from October 1996 to September 1998. During his early tenure with us, Mr. Levine resigned his position as Vice President, Sales and Marketing, Aesthetics Products which he held from September 1998 to January 2000, to join a start-up practice management organization, The Plastic Surgery Company, where he was Chief Development Officer until his resignation in September 2000. (More than a year after his resignation, in March 2002, The Plastic Surgery Company filed a voluntary petition in bankruptcy under Chapter 11 of the U.S. Bankruptcy Code.) Prior to his employment with us, Mr. Levine was employed by Kinetics Concepts, Inc., a specialty medical equipment manufacturer, in a variety of executive level sales and marketing positions, ultimately serving as Vice President and General Manager of KCI Home Health Care Division from 1989 to 1996. Mr. Levine earned his bachelor's degree in Communications from University of Arizona, Tucson.

**Loren L. McFarland** has served as Chief Financial Officer and Treasurer since May 2004. He was Vice President of Finance and Corporate Controller from 2001 to May 2004, Controller from 1989 to 2001, Assistant Controller from 1987 to 1989 and General Accounting Manager from 1985 to 1987. Prior to his employment with us, Mr. McFarland was employed by Touche Ross and Co., a public accounting firm, as a Certified Public Accountant and auditor from 1981 to 1985. Mr. McFarland earned his bachelor's degree in Business Administration and Accounting from the University of North Dakota and a master's degree in Business Administration from the University of California at Los Angeles.

**David J. Adornetto** has served as Vice President, Operations since December 2003. He was Corporate Vice President of Strategic Planning and Operational Development from August 2002 to December 2003, Vice President Finance for the Company's subsidiary, Mentor Medical Inc. from May 1999 to August 2002, Director of Finance for the Company's Manufacturing Operations Division from May 1997 to May 1999 and has held various other management positions since joining us in 1992. Prior to his employment with us, Mr. Adornetto was employed by Deloitte & Touche as a senior auditor. He is a Certified Public Accountant and earned his master's degree in Business Administration from the University of California at Los Angeles.

**Kathleen M. Beauchamp** has served as Vice President Sales & Marketing since December 2003 and as an officer since July 2004. She was Vice President of Aesthetic Sales between April 2002 and December 2003, and Director of Sales, Domestic Aesthetics from January 2000 to April 2002. Ms. Beauchamp has served as an Aesthetics sales representative, National Sales Trainer, Regional Manager, and National Sales Manager since her employment with us in May 1993, and has 20 years of experience in the healthcare industry, including pharmaceutical and biotechnology. Ms. Beauchamp is a graduate of Santa Clara University.

**A. Christopher Fawzy** has served as Vice President, General Counsel, and Secretary since October 2005. He was promoted to General Counsel in December 2003 and appointed to the office of Secretary in July 2004. He was Corporate Counsel, responsible for all legal functions of the Company from February 2002 to December 2003, and a Staff Attorney, responsible for the Company's contractual arrangements, commercial and product litigation, and general legal compliance from January 2001 to February 2002. Prior to his employment with us, Mr. Fawzy practiced law at Casey & Brannen, P.C., an Illinois-based law firm, where he focused on commercial and civil litigation. He earned his bachelor's degree in Economics from the University of Illinois, and his Doctorate of Jurisprudence from Northern Illinois University College of Law. Mr. Fawzy is a member of the State Bar of Illinois and is a Registered In-House Counsel member of the State Bar of California.

#### Available Information

We file with the Securities and Exchange Commission ("SEC") our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, proxy statements and registration statements. The public may read and copy any material we file with the SEC at the SEC's Public Reference Room at 100 F. Street, N.E., Room 1580, Washington, D.C. 20549. The public may also obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains its Internet site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding registrants, including us, that file electronically.

Our primary web site is <http://www.mentorcorp.com>. We make available free of charge, on or through this web site, our annual, quarterly and current reports and any amendments to those reports, as soon as reasonably practicable after electronically filing such reports with the SEC. In addition, copies of the written charters for the committees of our Board of Directors, our Corporate Governance Guidelines, our Code of Ethics for Senior Financial Officers, and our Code of Business Conduct and Ethics are also available on this web site, and can be found under the Investor Relations and Corporate Governance links. Copies are also available in print, free of charge, by writing to Mentor Corporation, 201 Mentor Drive, Santa Barbara, CA 93111, Attn: Investor Relations. We may post amendments or waivers about our Code of Ethics for Senior Financial Officers and Code of Business Conduct and Ethics, if any, on our web site. This web site address is intended to be an inactive textual reference only, and none of the information contained on our web site is part of this report or is incorporated in this report by reference.

#### **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.

**ITEM 1A. RISK FACTORS.**

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 coverages.***

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 offer product replacement and certain financial assistance for surgical procedures that fall within our limited warranty and coverage period of implantation on our breast implant products, and we accrue for those limited warranties. Such accruals are based on estimates, taking into consideration relevant factors such as historical experience, warranty period, estimated costs, existence and 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. We assess the adequacy of these accruals periodically and adjust the amounts as necessary based on actual experience and changes in future expectations. We also recently expanded our limited warranty programs to provide certain financial assistance for surgical procedures within ten years of implantation (increased from five years) and expanded the program coverage to include breast implant sales in European and certain other countries, in addition to the United States. Changes to actual warranty claims incurred could have a material impact on the actuarial analysis, which in turn could materially impact our reported expenses and results of operations.

In addition to product liability or warranty claims, we could experience a material design or manufacturing failure, a quality system failure, other safety issues, or heightened regulatory scrutiny that would warrant a recall of products we manufacture or are manufactured by another company and we distribute. A recall of some of our products could result in exposure to additional product liability claims, significant expense to perform the recall and lost sales.

***We are subject to substantial government regulation, which could have a material adverse affect on our business.***

The production and marketing of our products and our ongoing research and development activities, including 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. Certain of our products are required to undergo review by a panel of outside experts selected by the FDA, which makes a recommendation to the FDA as to whether the product(s) should or should not be approved. This process makes it potentially longer, more difficult and/or more costly to bring our products to market, and we cannot guarantee that any of our unapproved products will be approved or how long it may take for any one particular product to 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 manufacturing, packaging, labeling, storage, distribution, record-keeping, advertising, and marketing procedures. If we do not comply with applicable regulatory requirements, such violations could result in non-approval, suspensions of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, civil penalties and criminal fines, product seizures, operating restrictions, injunctions, and criminal prosecution.

Delays in, withdrawal, or rejection of the FDA or other government entity approval(s) of our products, including a delay in or rejection of the approval of our round silicone gel-filled breast implant pre-market approval application ("PMA") or a significant delay in acceptance of the clinical module of our Contour Profile Gel PMA, or any significant delays in our PMA filings, including our Puragen Plus<sup>®</sup>PMA, may also adversely affect our business. Such delays, withdrawals, or rejections may be encountered due to, among other reasons, government or regulatory delays, lack of demonstrated safety or efficacy during clinical trials, safety issues, manufacturing 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 or requirements in the U.S. and abroad. In the U.S., there has been a continuing trend toward more stringent FDA requirements in the areas of product approval and enforcement, causing medical device manufacturers to experience longer research and development timelines, 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, stringent post-marketing requirements, or may prevent us from broadening the uses of our current products for different applications. If we incur significant expenses, for example, in connection with post-market patient monitoring and data collection activities for our silicone gel-filled breast implants, this could have a material adverse effect on our results of operations. In addition, to the extent permissible by law, 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. We may also be required to withdraw or recall our products after we receive approvals and begin commercial sales if we, the FDA or a foreign government agency determines that there is a higher than average incidence of post-treatment complications with our products as a result of subsequent clinical experience and/or data. From time to time, we are subject to inquiry by government agencies in this regard.

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/or 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, but not limited to, product recalls, withdrawal of the product from the market or other enforcement actions.

From time to time, legislative or regulatory proposals are introduced that, if implemented, could alter the review and approval process relating to medical devices, or related to the sale of our products. It is possible that the FDA or other governmental authorities will issue additional regulations, which could further reduce or restrict the sales of our presently marketed products or products under development.

Any change in legislation or regulations that govern the review and approval process relating to our current and/or future products, or that restrict the manner by which we may sell our products, could make it more difficult and/or costly to obtain approval for new products, and/or to produce, market, and distribute existing products.



*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 research and development, product improvement programs, and required clinical studies to develop new technologies and to maintain and improve our competitive position. Any significant delays in the above or termination or failure of our clinical trials would materially and adversely affect our research, 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 or success in the marketplace.

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, user/patient acceptance, and our marketing and distribution capabilities. Physicians will not recommend our products if clinical and/or other data and/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.

In December 2003, we completed our PMA application to the FDA for our silicone gel-filled implants for breast augmentation, reconstruction and revision. In August 2004, we amended our PMA application based on a revised draft guidance released by the FDA in January 2004. On July 28, 2005, we received an "approvable" letter, with conditions, from the FDA on our PMA application for our silicone gel-filled breast implants. The approvable letter stipulates a number of conditions which we must satisfy in order to receive FDA approval to market and sell silicone gel-filled breast implants in the United States. Our current discussions with FDA regarding our MemoryGel<sup>®</sup> silicone gel-filled breast implant PMA are primarily focused on post-approval patient monitoring and data collection. Despite the approvable letter and our current discussions, the FDA may ultimately decide to not approve our silicone gel-filled breast implants for sale in the United States, or if they do approve, the FDA would most likely recommend additional post-approval conditions or requirements, for which we would incur costs that could be substantial, and which could potentially impact our sales and earnings, depending on the scope and complexity of the requirements. Further change in FDA regulatory requirements, including those implemented through new or revised FDA guidance, (such as that announced on January 8, 2004 by the FDA), may delay or may otherwise adversely affect our pending PMA application as well as its review or approval by the FDA. A delay or denial response by the FDA would have a material adverse effect on our commercialization timelines and competitive position, and ultimately our revenue and operating results. If our new products do not achieve significant market acceptance, or if our current products do not continue competing successfully in the changing market, our sales and earnings may not grow as much as expected, or may even decline.

We also have two pending applications for Medical Device Licenses in Canada for our silicone gel-filled breast implants. An expert advisory panel was convened by the Canadian government on March 22, 2005 to review our pending application for Medical Device Licenses. A public forum called by Health Canada on these devices was held September 29, 2005. We cannot predict the outcome of these reviews, nor determine when or if Health Canada will approve our product applications. In addition, any approval could be granted with stringent post-approval conditions or requirements, for which we would incur costs, and which could impact our sales and earnings, depending on the scope and complexity of such requirements.

With respect to our Puragen Plus<sup>™</sup> program in the U.S., we recently identified potential issues that required further evaluation of our clinical study data that will result in a delay to our PMA submission timeline. We performed this further evaluation, and we concurrently reviewed some of our critical production processes. Though we have developed a plan to move forward with our Puragen Plus<sup>™</sup> PMA process, any further delays in the submission of our PMA or a delay or denial response by the FDA would have a material adverse effect on our commercialization timelines and competitive position, and ultimately our future revenue and operating results.

***If we are unable to compete effectively with existing or new competitors, we could experience price reductions, reduced demand for our products, reduced margins and loss of market share, and our business, results of operations and financial condition would be adversely affected.***

Our products compete with similar or other competitive medical products manufactured by major companies, and may also compete with new products currently under development by others.

Competition in our industry occurs on a variety of levels, including but not limited to:

developing and bringing new products to market before others or to provide benefits superior to those of existing products;

developing new technologies to improve existing products;

developing new products at a lower cost to provide the same benefits as existing products at the same or lower price;

creating or entering new markets with existing products;

increasing or improving service-related programs; and

advertising in a manner that creates additional awareness and demand.

The competitive environment requires an ongoing, extensive search for technological innovations and the ability to market products effectively. Consequently, we must continue to effectively execute on various competitive levels to properly position our products in the marketplace and maintain our market share, revenue and gross margins.

In particular, we face competition from Allergan, Inc., which acquired Inamed Corporation in March 2006, our only current competitor in the U.S. for our breast aesthetics product line. On September 21, 2005, Inamed announced that it also received an "approvable" letter, with conditions, from the FDA for its silicone gel-filled breast implants. If Allergan gains FDA approval to market its silicone gel-filled breast implant products before we do, our competitive position will likely suffer. As a result of Allergan's acquisition of Inamed, we are now competing against a much larger competitor with a substantially larger sales force.

***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 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. For example, we may be required to recall or withdraw our products if we, the FDA or a foreign government agency determine that use of our products results in a higher than average rate of post-treatment complications based on clinical experience and/or data. If one foreign government agency were to request or require a withdrawal or recall of one or more of our products, the safety concerns leading to that government agency's request may be investigated by regulatory bodies in other countries, which could result in additional withdrawals or recalls and could result in negative publicity regarding our products. 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 and body contouring, are not covered by insurance. Adverse changes in the economy or other conditions or events 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.

***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.***

In fiscal 2004, we implemented an enterprise resource planning system at our major locations which is our primary business management system. We intend to continue to implement the system for substantially all of our businesses worldwide. Many other companies have had severe problems with computer system implementations 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 projects 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. In October 2005, we announced our intention to refocus our business solely on aesthetic medicine and we sold our surgical urology and clinical and consumer health businesses in June 2006. This refocus consumed a significant amount of management attention and may have distracted and may continue to distract us from pursuing acquisition opportunities in the short term. We intend to continue to acquire other businesses and technologies to facilitate our future business strategies. 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. For example, in November 2005, we made an unsolicited offer to acquire Medicis, Inc. (which was at the time subject to an acquisition agreement with Inamed) that was rejected. We may incur substantial expenses in connection with our acquisition activities, even if the transaction is not completed, such as the approximately \$3.4 million in expenses incurred related to the offer to acquire Medicis. 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.

***We may suffer from disruptions to our business and information technology systems and be unable to retain employees as a result of the June 2006 sale of our Urology Business to Coloplast.***

In October 2005, we announced our intention to refocus our business solely on aesthetic medicine, and we completed the sale of our surgical urology and clinical and consumer health businesses to Coloplast in June 2006. As a result of the transition of employees, information technology services, facilities and customers to Coloplast, our business may be disrupted. For example, we may experience difficulty with our enterprise resource planning system due to the separation of the Urology Business segment from our existing system.

***We are obligated to provide specified transition services to Coloplast and our ability to complete our own planned projects may suffer if the resource requirements for providing those services exceeds our expectations.***

We are obligated to provide a variety of transition services to Coloplast in connection with their acquisition of our Urology Business for up to 12 months. The demands on us associated with providing these services may outpace our expectations and we may be obligated to devote more resources than we expect to provide the services, and may divert management's attention.

***We agreed to indemnify Coloplast against specified losses in connection with Coloplast's purchase of our Urology Business and any demands for indemnification may result in expenses we do not anticipate and distract the attention of our management from our continuing businesses.***

We have agreed to indemnify Coloplast against specified losses in connection with the June 2006 sale of our Urology Business and generally retain responsibility for various legal liabilities that accrue prior to closing. We also made representations and warranties to Coloplast about the condition of our Urology Business, including matters relating to intellectual property, regulatory compliance and environmental laws. If Coloplast makes an indemnification claim because it has suffered a loss or a third party has commenced an action against Coloplast, we may incur substantial expenses resolving Coloplast's claim or defending Coloplast and ourselves against the third party action, which would harm our operating results. In addition, our ability to defend ourselves may be impaired because our former Urology Business employees are now employees of Coloplast and our management may have to devote a substantial amount of time to resolving the claim, and, as we are no longer in the Urology Business, will not be able to readily offer products, service and intellectual property in settlement. In addition, these indemnity claims may divert management attention from aesthetics business. It may also be difficult to determine whether a claim from a third party stemmed from actions taken by us or Coloplast and we may expend substantial resources trying to determine which party has responsibility for the claim.

***We may not realize some of the benefits of the Coloplast transaction.***

We anticipate that we will be able to utilize approximately \$7.9 million of foreign tax credits resulting from the Coloplast transaction. While Coloplast has agreed to indemnify us for the availability of up to \$7.1 million of these tax credits, we cannot be sure that we will be able to utilize those tax credits before they expire due to any number of factors including, but not limited to, whether the credits expire due to changes in ownership in excess of the applicable tax rules, sufficient income in the jurisdictions in which we have the credits and other possible reasons the tax credits might be disallowed. Although Coloplast has agreed to indemnify Mentor for \$7.1 million of the foreign tax credits, if the foreign tax credits are disallowed and we are not able to recover from Coloplast, we may not be able to realize the full amount, or any, of those tax credits.

***We may not be successful in transitioning our business to focus solely on aesthetic medicine, which may harm our prospects and operating results.***

As of June 2006, we completed the divestiture of our Urology Business, and our continuing business is now focused on aesthetic medicine. We may not successfully improve our operating margins despite the divestiture of our Urology Business to be consistent with those of competitive companies focused solely on aesthetic medicine. In addition, we may be unsuccessful at broadening the focus of our sales force to physicians practicing aesthetic medicine other than plastic surgeons. In order to successfully increase our sales presence to those physicians, we will be required to develop internally or purchase additional products that will meet the needs of those physicians and obtain regulatory approval to sell those products. For example, we have announced a delay in the anticipated date for submission of our Puragen Plus<sup>TM</sup> products to the FDA, which product would be marketed to dermatologists as well as plastic surgeons.

***State legislatures and taxing authorities may create new laws or change their interpretation of existing state and local tax laws that may affect future product demand or create unforeseen tax liabilities.***

If any state legislature or other government authority creates new laws to assess sales taxes on medical procedures determined by them to be cosmetic, our physician and patient customers may have to pay more for our products and future demand may decrease. In addition, if taxing authorities determine that our products are cosmetic and thus taxable based on their interpretations of existing tax laws or that our products are otherwise taxable, they may disallow currently available exemptions related to medical products and procedures. Such taxing authorities may then determine that we owe additional taxes related to product sales from prior periods. These determinations would have a negative effect on our results of operations.

***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, indemnification, 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 current or future technologies of our existing operations or those current technologies of our discontinued operations, 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 or indemnification obligations 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 used in many of our products, including silicone. 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 and suppliers for components and licensed products. In connection with the sale of our Urology Business to Coloplast, we have entered into a supply agreement with Coloplast for certain components of our breast implant products. For the short-term, Coloplast would be our sole source for these components, and if we were unable to obtain the supply, our business would be harmed. We may determine that we do not want to continue to purchase products from Coloplast or Coloplast may be unable to meet our needs in a timely manner, either of which may disrupt our business during the period we negotiate a supply agreement with and qualify the manufacturing process of a third party or begin production of the components ourselves. In addition, we depend on Niadyne, Inc. for the supply of NIA-24 and if we were no longer able to satisfy demand for this product through our relationship with Niadyne, our business could be harmed. If there is a disruption in the supply of any of these single or sole source products, our future sales and profitability would be adversely affected.

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

More than one-quarter of our sales for our continuing operations 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 products;
- 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
- completion.

***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 partially depend 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 result in contamination or injury, we could suffer significant financial loss.***

We are subject to federal, state, local and foreign environmental laws and regulations. Our manufacturing and research and development activities involve the controlled use of potentially hazardous materials, chemicals and biological materials, which require compliance with various laws and regulations regarding the use, storage, and disposal of such materials. We believe our continuing and discontinued operations comply in all material respects with applicable environmental laws and regulations in each country where we have a business presence.

Although we continue to make expenditures for environmental protection, we do not anticipate any additional significant expenditures, in complying with such laws and regulations, that would have a material impact on our earnings or competitive position. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse effect on our financial position. We cannot assure, however, that environmental claims or indemnification obligations relating to our continuing or discontinued operations, or properties currently or previously owned or operated by us will not develop in the future, nor can we predict whether any such claims, if they were to develop, would require significant expenditures on our part. 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 coverage. In addition, we are unable to predict what legislation or regulations may be adopted or enacted in the future with respect to environmental protection and waste disposal.

We are subject to regulation by the United States Environmental Protection Agency and other state and local environmental agencies in each of our domestic manufacturing facilities. For example, in Texas, we are subject to regulation by the local Air Pollution Control District as a result of some of the chemicals used in our manufacturing processes. Prior to the June 2, 2006 Coloplast transaction, we were also subject to regulation by the United States Nuclear Regulatory Commission in our Oklahoma facility due to the manufacture and distribution of brachytherapy seeds using radioactive iodine I-125 and palladium Pd-103. We may have continuing liability for any violations which arose prior to the Coloplast transaction. In our Wisconsin facility, we are also subject to regulation by the U.S. Department of Health and Human Services, Centers for Disease Control, due to the nature of the biological agent used to manufacture our botulinum toxin product, *Clostridium botulinum* type A, which is still in the development phase. Failure to comply with the regulations and requirements of these various agencies could affect our ability to manufacture products and may have a significant negative impact on sales and results of operations.

***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. 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 and require restatement of previously issued results for retroactive application of the new accounting standard. This was evidenced by the adoption of EITF 04-8 in the quarter ended December 2004, resulting in the restatement of diluted earnings per share and weighted average shares outstanding, for fiscal year 2004 and the interim periods ending June 30, and September 30, 2004.

***Changes in the accounting treatment of stock-based awards will adversely affect our reported results of operations.***

In December 2004 the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 123 (revised 2004), Share-Based Payment, or SFAS 123(R), which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation, or SFAS 123. SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their grant date fair values and does not allow the previously permitted disclosure-only method as an alternative to financial statement recognition. Effective April 1, 2006 we adopted SFAS 123(R).

The adoption of the SFAS 123(R) fair value method will have a significant adverse impact on our reported results of operations because the stock-based compensation expense will be charged directly against our reported earnings. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that we grant additional equity securities to employees or assume unvested securities in connection with any acquisitions, our stock-based compensation expense will be increased by the additional unearned compensation resulting from those additional grants or acquisitions. We anticipate we will grant additional employee stock options and restricted stock in the first quarter of fiscal 2007 as part of our regular annual equity compensation program. The fair value of these grants is not included in the amount above, as the impact of these grants cannot be predicted at this time because it will depend on the number of share-based payments granted as part of the focal review program and the then current fair values.

Had we adopted SFAS 123(R) in prior periods, the magnitude of the impact of that standard on our results of operations would have approximated the impact of SFAS 123 assuming the application of the Black-Scholes option pricing model as described in the disclosure of pro forma net income and pro forma net income per share in Note G of Notes to Consolidated Financial Statements. SFAS 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement may reduce net operating cash flows and increase net financing cash flows in periods after its adoption.

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

In connection with the original issuance of our 2¾% convertible subordinated 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 approximately \$39.26 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, business partners, distributors, shareholders, 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 securities, including our common stock or our convertible notes.



*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 March 31, 2006, the closing price of our common stock on the New York Stock Exchange was \$45.31 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 2¾% per annum, are convertible into shares of our common stock at an adjusted conversion price of \$29.167 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 including such factors 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 convertible 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 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

We own and lease the following facilities:

Location	Total Sq. Ft.	Principal Segment and Use
<b><u>Owned Properties</u></b>		
Netherlands	65,000	Manufacturing, warehousing and administrative offices
Minnesota	20,000	Manufacturing, warehousing
	85,000	
<b><u>Leased Properties</u></b>		
Texas	134,000	Manufacturing, warehousing and administrative offices:
California	127,000	Corporate offices, research and development, and sales and marketing
Arizona	32,000	Manufacturing, warehousing and administrative offices
United Kingdom	23,000	Manufacturing, warehousing and administrative offices

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Canada 11,000 Sales, warehousing and administrative offices

Wisconsin 10,000 Research and development

337,000

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Our property in The Netherlands is pledged as collateral on borrowings under a Loan and Overdraft Facility with Cooperative RaboBank Leiden. See "Liquidity and Capital Resources" under Item 7A - "Management's Discussion and Analysis of Financial Condition and Results of Operations" for additional information. Our leases have terms ranging from 1 to 15 years, many of which have options to renew on terms we consider favorable. In addition to the facilities mentioned above, we have international sales offices throughout eight countries where we lease office and warehouse space ranging from 1,000 to 8,000 square feet. We anticipate that we will be able to extend or renew the leases that expire in the near future on terms satisfactory to us, or if necessary, locate substitute facilities on acceptable terms.

We believe our facilities are generally suitable and adequate to accommodate our current operations and additional suitable facilities are readily available to accommodate future expansion as necessary.

For information regarding lease obligations see Note N "Commitments" under "Notes to the Consolidated Financial Statements."

**ITEM 3. LEGAL PROCEEDINGS.**

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 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, who was a member of our Board of Directors from March 1990 until his retirement on March 1, 2006, was also a partner of PTF and was 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. Pursuant to Dr. Young's request, the PTF Partnership Agreement was amended to permit withdrawal of partners from the PTF Royalty Partnership upon notice. On June 3, 2005, Dr. Young submitted his notice of withdrawal to the Partnership, and a joint stipulation removing Dr. Young from the caption of the complaint and as a named party to the litigation was entered by the court in June 2005.

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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

No matters were submitted for a vote of our shareholders during the fourth quarter of the fiscal year ended March 31, 2006.

**PART II****ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

Our common stock trades on the New York Stock Exchange under the symbol "MNT". The high and low quarterly closing sales prices of our common stock, as reported by the NYSE for the two most recent fiscal years are set forth below.

<u>Year Ended March 31, 2006</u>		<u>High</u>		<u>Low</u>
Quarter ended March 31, 2006	\$	49.20	\$	41.60
Quarter ended December 31, 2005	\$	56.14	\$	43.54
Quarter ended September 30, 2005	\$	55.99	\$	41.21
Quarter ended June 30, 2005	\$	43.03	\$	31.90

<u>Year Ended March 31, 2005</u>		<u>High</u>		<u>Low</u>
Quarter ended March 31, 2005	\$	35.80	\$	29.98
Quarter ended December 31, 2004	\$	35.18	\$	29.20
Quarter ended September 30, 2004	\$	35.94	\$	29.59
Quarter ended June 30, 2004	\$	34.43	\$	29.80

According to the records of our transfer agent, there were approximately 860 holders of record of our common stock on June 11, 2006. However, the majority of shares are held by brokers and other institutions on behalf of shareholders.

Dividend Policy

We periodically declare cash dividends on our common stock. It is our intent to continue to pay dividends for the foreseeable future subject to, among other things, Board approval, cash availability, limitations under our existing credit facility, and alternative cash needs. Our existing credit agreement limits the aggregate amount of dividends payable in any fiscal year to 60% of our net income for the four most recent fiscal quarters.

	Quarterly Cash Dividends Declared			
	Year Ended March 31,			
	<b>2006</b>	2005	2004	
First Quarter	\$ <b>0.17</b>	\$ 0.15	\$ 0.02	
Second Quarter	<b>0.18</b>	0.17	0.15	
Third Quarter	<b>0.18</b>	0.17	0.15	
Fourth Quarter	<b>0.18</b>	0.17	0.15	
Total	\$ <b>0.71</b>	\$ 0.66	\$ 0.47	



Issuer Purchases of Equity Securities

Our Board of Directors has authorized a stock repurchase program, primarily to offset the dilutive effect of our employee stock option plans, 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. The timing of repurchases is subject to market conditions, cash availability, and blackout periods during which we are restricted from repurchasing shares. On May 31, 2006 we amended our Credit Agreement to expand the amount of equity securities we can repurchase to \$250 million plus a subsequent amount during any four consecutive quarters equal to our consolidated net income less dividends paid for the preceding four quarters. On June 5, 2006, we repurchased 2.0 million shares for a total of \$84 million from an investment partnership managed by ValueAct Capital, whose managing director, Mr. Jeff Ubben, is a member of our Board of Directors. The repurchase of these shares was pre-approved by our Audit Committee and the majority of our Board of Directors with interested parties abstaining or not in attendance. As a result of this repurchase, 3.3 million shares remain authorized for repurchase, and \$166.0 million plus additional amounts equivalent to our consolidated net income, less dividends, remains available under our Credit Agreement limitations. The table below sets forth certain share repurchase information for the quarter ended March 31, 2006.

**ISSUER PURCHASES OF EQUITY SECURITIES**

(in thousands except per share amounts)	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
<b>Fourth Quarter 2006</b>				
January 1 - January 31, 2006	-	-	-	1,254
February 1 - February 28, 2006	-	-	-	1,254
March 1 - March 31, 2006	0.996	\$ 43.00	0.996	5,258
Total	0.996	\$ 43.00	0.996	5,258

a. In the first quarter of fiscal 1996, our Board of Director's authorized an ongoing stock repurchase program. The initial authorization was for the repurchase of up to one million shares. Subsequently the Board of directors has authorized the repurchase of an additional 24.2 million shares including 5.0 million, 2.2 million and 5.0 shares in March 2006, May 2003 and December 2003, respectively. These share amounts have been adjusted for the two-for-one stock split affected December 2002.

b. We have not set a date for the stock repurchase program to expire.

We intend to repurchase shares during fiscal 2007 through a plan under Rule 10b5-1, which we anticipate adopting during the first quarter fiscal 2007. The first purchases under the 10b5-1 plan will not occur until after the public announcement of our results for the quarter ending June 30, 2006. We cannot estimate or guarantee the amount of shares to be repurchased under this plan.

**ITEM 6. SELECTED FINANCIAL DATA.**

The selected consolidated financial information presented below is obtained from our audited consolidated financial statements for each of the five fiscal years ending March 31, 2006. This selected financial data should be read together with our consolidated financial statements and related notes, as well as the discussion under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(in thousands, except per share data)	Year Ended March 31,				
	2006	2005	2004	2003	2002
<b>Statement of Income Data:</b>					
Net sales	\$ 268,272	\$ 251,726	\$ 218,437	\$ 191,404	\$ 163,091
Gross profit	199,063	187,150	157,854	137,544	113,401
Operating income from continuing operations	69,065	65,381	66,206	57,506	40,900
Income before income taxes -					
continuing operations	67,685	62,745	67,251	59,066	43,128
Income taxes - continuing operations	19,606	19,937	21,479	17,186	12,114
Income from continuing operations	48,079	42,808	45,772	41,880	31,014
Discontinued operations, net of income tax <sup>(1)</sup>	14,278	12,073	9,007	13,940	10,806
Net income	\$ 62,357	\$ 54,881	\$ 54,779	\$ 55,820	\$ 41,820
Basic earnings per share <sup>(2)</sup> :					
Continuing operations	\$ 1.12	\$ 1.02	\$ 1.00	\$ 0.90	\$ 0.65
Discontinued operations <sup>(1)</sup>	0.33	0.29	0.20	0.30	0.23
Basic earnings per share	\$ 1.45	\$ 1.31	\$ 1.20	\$ 1.20	\$ 0.88
Diluted earnings per share <sup>(2)</sup> :					
Continuing operations	\$ 1.01	\$ 0.93	\$ 0.95	\$ 0.86	\$ 0.63
Discontinued operations <sup>(1)</sup>	0.28	0.24	0.18	0.29	0.22
Diluted earnings per share	\$ 1.29	\$ 1.17	\$ 1.13 <sup>(2)</sup>	\$ 1.15	\$ 0.85
Dividends per common share	\$ 0.71	\$ 0.66	\$ 0.47	\$ 0.07	\$ 0.06
Average outstanding shares <sup>(2)</sup> :					
Basic	42,995	41,921	45,543	46,428	47,278
Diluted	50,870	49,667	49,272 <sup>(3)</sup>	48,388	48,926
<b>Balance Sheet Data:</b>					
Working capital	\$ 210,019	\$ 148,434	\$ 149,981	\$ 134,863	\$ 104,609
Total assets	400,518	311,962	312,236	241,480	206,193
Long-term accrued liabilities, less current portion	18,984	15,385	13,597	10,777	7,432
Convertible subordinated notes	150,000	150,000	150,000	-	-
Shareholders' equity	\$ 226,589	\$ 172,527	\$ 196,004	\$ 276,136	\$ 226,602

(1) In June 2006, we sold our surgical urology and clinical and consumer healthcare businesses. As a result, the operations for these former businesses have been reflected as discontinued operations for all prior periods. See "Note T - Discontinued Operations" in the "Notes to the Consolidated Financial Statements."

(2) Per share amounts and shares outstanding have been adjusted to reflect a two-for-one stock split effected January 21, 2003.

(3) Per share amounts and diluted shares outstanding for fiscal 2004 have been restated to reflect the additional shares that would be issued upon conversion of our 2¾% convertible notes, in accordance with the adoption of Emerging Issue Task Force (EITF) Issue No. 04-8 in the quarter ended December 2004.





**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

The following discussion should be read together with our consolidated financial statements and related notes, which are included in this report, and the information in the "Item 1A. Risk Factors" section of this report.

**OVERVIEW**

We develop, manufacture and market a range of products serving the aesthetic medicine market, including plastic and reconstructive surgery. Our products include surgically implantable prosthesis for plastic and reconstructive surgery, as well as capital equipment and consumables used for soft tissue aspiration for body contouring (liposuction). Historically, we operated in three reportable segments: aesthetic and general surgery, surgical urology, and clinical and consumer healthcare. Our surgical and urology products included 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 included catheters and other products for the management of urinary incontinence and retention. In October 2005, we began to evaluate strategic alternatives for our surgical urology and clinical and consumer healthcare businesses. On May 17, 2006, we entered into a definitive purchase agreement to sell our Urology Business to Coloplast A/S for total consideration of \$463 million (\$456 million in cash and the remainder consisting of the value of certain foreign tax credits that we expect to realize arising from the transaction prior to the close). On June 2, 2006, the sale of the Urology Business was completed. On June 1, 2006, our Porges SAS subsidiary sold certain intellectual property to Coloplast for \$52 million, which is included in the total consideration of \$463 million. The purchase price is subject to a post-closing adjustment based on the working capital of the acquired business as of the closing date, and a downward reduction in an amount equal to 50% of the amount of certain transfer taxes and related fees incurred in connection with the transaction, 50% of the cost of severance obligations in respect of certain former employees of the Urology Business who will not continue with the Urology Business following the closing of the transaction, and certain other administrative costs.

The purchase agreement with Coloplast contains customary representations and warranties and indemnification provisions whereby each party agrees to indemnify the other for breaches of representations and warranties, breaches of covenants and other matters, with our liability for breaches of representations and warranties generally limited to 15% of the purchase price. Pursuant to the terms of the purchase agreement, an escrow fund was established with \$10 million withheld from the purchase price to secure our indemnification obligations with respect to any breaches of our representations and warranties for a period of 18 months. In addition, the purchase agreement provides that we will not enter into or engage in a business that competes with the Urology Business, on a worldwide basis, for a period of seven years following the closing of the transaction. These restrictions on competition do not apply to (i) the development, manufacture or sale of any oral pharmaceuticals or any product or treatments involving dermal fillers or other bulking agents or toxins, including botulinum toxins, or (ii) any business acquired and operated by us or our affiliates for so long as any such businesses generate less than \$5 million in aggregate annual revenues from any competing business. These restrictions on competition terminate upon a change in control of Mentor.

In connection with the sale to Coloplast, we also entered into a Transition Services Agreement and various supply agreements. Pursuant to the Transition Services Agreement, in exchange for specified fees, we will provide to Coloplast and Coloplast will provide to us, services including accounting, information technology, customer support and use of facilities. Under the supply agreements we will supply various products, including silicone gel-filled testicular implants to Coloplast and Coloplast will supply us with components for the manufacture of our breast implants. These services agreements are expected to extend through a period not to exceed twelve months and the supply agreements range from a period of 6 - 36 months. These services and supply agreements are not expected to have a significant impact on our future cash flows from continuing operations.

On June 2, 2006, we also completed the sale of our intellectual property, raw materials and tangible assets for the production of silicone male external catheters relating to our catheter production facility in Anoka, Minnesota and our inventory of such catheters to Rochester Medical Corporation, for an aggregate purchase price of approximately \$1.6 million.

As a result of the sale to Coloplast, the assets and liabilities related to the Urology Business have been segregated from continuing operations and are reported as assets and liabilities of discontinued operations in the accompanying consolidated balance sheets. In addition, operations associated with the Urology Business have been classified as income from discontinued operations in the accompanying consolidated statements of income. Prior to being designated as discontinued operations, the Urology Business contributed approximately 47% of our consolidated net sales and approximately 27% of our operating profit in fiscal year 2006. We will record a net gain on the sale of our Urology Business in the first quarter of fiscal 2007. As a result of this sale, we will be able to focus on the aesthetic medicine market. We intend to leverage our traditional strengths in plastic surgery and grow our market presence in cosmetic dermatology.

### **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.

We believe the following critical accounting policies, among others, affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

#### **Revenue Recognition**

We recognize product revenue, net of discounts, returns, and rebates in accordance with Statement of Financial Accounting Standards ("SFAS") No. 48, "Revenue Recognition When the Right of Return Exists," and Staff Accounting Bulletin ("SAB") No. 104, "Revenue Recognition."

As required by these standards, revenue is recorded when persuasive evidence of a sales arrangement exists, delivery has occurred, the buyer's price is fixed or determinable, contractual obligations have been satisfied, and collectibility is reasonably assured. These requirements are met, and sales and related cost of sales are recognized, upon the shipment of products, or in the case of consignment inventories, upon the notification of usage by the customer. We record estimated reductions to revenue for customer programs and other volume-based incentives. Should the actual level of customer participation in these programs differ from those estimated, additional adjustments to revenue may be required. We also allow credit for products returned within our policy terms. We record an allowance for estimated returns at the time of sale based on historical experience, recent gross sales levels and any notification of pending returns. Should the actual returns differ from those estimated, additional adjustments to revenue and cost of sales may be required.

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Our deferred revenue consists of both current and long term and includes funds received in connection with sales of our Enhanced Advantage Breast Implant Limited Warranty program. The fees received in connection with a sale of an Enhanced Advantage Breast Implant Limited Warranty are deferred and recognized as revenue evenly over the life of the warranty term.

### Accounts Receivable

We market our products to a diverse customer base, principally throughout the United States, Canada, Western Europe, Central and South America, and the Pacific Rim. We grant credit terms in the normal course of business to our customers, primarily hospitals, doctors and distributors. We perform ongoing credit evaluations of our customers and adjust credit limits based upon payment history and the customer's current credit worthiness, as determined through review of their current credit information. We continuously monitor collections and payments from customers and maintain allowances for doubtful accounts for estimated losses resulting from the inability of some of our customers to make required payments. Estimated losses are based on historical experience and any specifically identified customer collection issues. If the financial condition of our customers, or the economy as whole, were to deteriorate resulting in an impairment of our customers' ability to make payments, additional allowances may be required. These additional allowances for estimated losses would be included in selling, general and administrative expenses.

### Inventories

We value our inventory at the lower of cost, based on the first-in first-out ("FIFO") cost method, or the current estimated market value of the inventory. We write down our 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. If actual future demand or market conditions differ from those projected by us, additional inventory valuation adjustments may be required. These additional valuation adjustments would be included in cost of sales.

### Warranty Reserves

We offer two types of warranties relating to our breast implants in the United States, Canada, and Puerto Rico: a standard limited warranty which is offered at no additional charge and an enhanced limited warranty at an additional charge of \$100 in the U.S. (\$100 CAD in Canada), which provide limited financial assistance in the event of a deflation or rupture. Our standard limited warranty is also offered in certain European and other international countries for silicone gel-filled breast implants. We provide an accrual for the estimated cost of breast implant warranties at the time revenue is recognized. Costs related to warranties are recorded in cost of sales. The estimated cost of the standard limited warranty is recorded as an expense at the time of sale, whereas the estimated cost of the enhanced limited warranty is deferred and recognized over the term of the enhanced limited warranty which approximates costs as incurred. Such accruals are based on estimates, which are based on relevant factors such as unit sales, historical experience, the limited warranty period, estimated costs, and, to a limited extent, information developed by our insurance company using actuarial techniques. These accruals are analyzed periodically for adequacy. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of our component suppliers, the warranty obligation is affected by reported rates of warranty claims and levels of financial assistance specified in the limited warranties. Should actual patient claim rates reported differ from our estimates, adjustments to the estimated warranty liability may be required. These adjustments would be included in cost of sales.

### Product Liability Reserves

We have product liability reserves for product-related claims to the extent those claims may result in litigation expenses, settlements or judgments within our self-insured retention limits. We have also established additional reserves, through our wholly-owned captive insurance company, for estimated liabilities for product-related claims based on actuarially determined estimated liabilities, taking also into account our excess insurance coverages. The actuarial valuations are based on historical information and certain assumptions about future events. Product liability costs are recorded in selling, general and administrative expenses as they are directly under the control of our General Counsel and other general and administrative staff and are directly impacted by our overall corporate risk management strategy. Should actual product liability experience differ from the estimates and assumptions used to develop these reserves, subsequent changes in reserves will be recorded in selling, general and administrative expenses, and may affect our operating results in future periods.



Goodwill and Intangible Asset Impairment

We evaluate long-lived assets, including goodwill and other intangibles, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In addition, we evaluate goodwill and other intangibles annually in the fourth quarter of each fiscal year. In assessing the recoverability of goodwill and other intangibles, we must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. We adopted SFAS No. 142, "Goodwill and Other Intangible Assets," effective April 1, 2002 and analyzed goodwill and intangibles for impairment. Impairment tests were performed at adoption, and in the fourth quarter of fiscal years 2003, 2004 and 2006, and no impairment was noted as a result of these analyses. The impairment tests performed in fiscal 2005 indicated certain impaired assets, for which we recorded impairment charges in fiscal 2005. These impairment charges are included in the results of operations. See Note I - "Intangible Assets and Goodwill" of the "Notes to the Consolidated Financial Statements."

Stock-Based Compensation Expense for Fiscal 2007 and Thereafter

Effective April 1, 2006 we adopted SFAS No. 123 (revised 2004), Share-Based Payment, or SFAS 123(R). SFAS 123(R) requires all share-based payments, including grants of stock options, restricted stock units and employee stock purchase rights, to be recognized in our financial statements based on their respective grant date fair values. Under this standard, the fair value of each employee stock option and employee stock purchase right is estimated on the date of grant using an option pricing model that meets certain requirements. We currently use the Black-Scholes option pricing model to estimate the fair value of our share-based payments. The Black-Scholes model meets the requirements of SFAS 123(R) but the fair values generated by the model may not be indicative of the actual fair values of our stock-based awards as it does not consider certain factors important to stock-based awards, such as continued employment and periodic vesting requirements and limited transferability. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. We use the implied volatility for traded options on our stock as the expected volatility assumption required in the Black-Scholes model. Our selection of the implied volatility approach is based on the availability of data regarding actively traded options on our stock as we believe that implied volatility is more representative than historical volatility. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our stock options and stock purchase rights. The dividend yield assumption is based on our history and expectation of dividend payouts. The fair value of our restricted stock units is based on the fair market value of our common stock on the date of grant. Stock-based compensation expense recognized in our financial statements in fiscal 2006 and thereafter is based on awards that are ultimately expected to vest. The amount of stock-based compensation expense in fiscal 2007 and thereafter will be reduced for estimated forfeitures based on historical experience. Forfeitures are required to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. We will evaluate the assumptions used to value stock awards on a quarterly basis. If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase or cancel any remaining unearned stock-based compensation expense. To the extent that we grant additional equity securities to employees or we assume unvested securities in connection with any acquisitions, our stock-based compensation expense will be increased by the additional unearned compensation resulting from those additional grants or acquisitions. Had we adopted SFAS 123(R) in prior periods, the magnitude of the impact of that standard on our results of operations would have approximated the impact of SFAS 123 assuming the application of the Black-Scholes option pricing model as described in the disclosure of pro forma net income and pro forma net income per share in Note G of our "Notes to Consolidated Financial Statements".

**RESULTS OF OPERATIONS**

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

	Year Ended March 31,		
	2006	2005	2004
Net sales	<b>100.0%</b>	100.0%	100.0%
Cost of sales	<b>25.8%</b>	25.7%	27.7%
Gross profit	<b>74.2%</b>	74.3%	72.3%
Selling, general, and administrative	<b>37.7%</b>	34.3%	32.3%
Research and development	<b>10.8%</b>	10.0%	9.7%
Severance charges	-	3.0%	-
Restructuring and long-lived asset impairment charges	-	1.0%	-
Operating income	<b>25.7%</b>	26.0%	30.3%
Interest expense	<b>(2.1)%</b>	(2.0)%	(0.7)%
Interest income	<b>1.5%</b>	0.7%	0.7%
Other income, net	<b>0.1%</b>	0.2%	0.5%
Income before income taxes	<b>25.2%</b>	24.9%	30.8%
Income taxes	<b>7.3%</b>	7.9%	9.8%
Net income from continuing operations	<b>17.9%</b>	17.0%	21.0%
Net income from discontinued operations	<b>5.3%</b>	4.8%	4.1%
Net income	<b>23.2%</b>	21.8%	25.1%

**YEARS ENDED MARCH 31, 2006 AND 2005****Sales**

Net sales increased 7% to \$268.3 million from \$251.7 million in the prior year. Net sales of breast implant products increased 7% to \$233.2 million from \$217.4 million in the prior year. The majority of the increase in breast implant product sales is attributable to organic growth in unit sales of our breast implants and associated products. Foreign exchange rate movements, primarily the Euro, had a minimal year-t