MENTOR CORP /MN/
Form 10-K
May 30, 2008

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

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

For the fiscal year ended
March 31, 2008
or

o **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	**41-0950791**
(State or other jurisdiction of incorporation or organization)	(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)
Securities registered pursuant to 12(b) of the Act:

Title of Each Class:	**Name of Each Exchange on Which Registered**
Common Shares, par value $0.10 per share	New York Stock Exchange

Securities registered pursuant to 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 þ No o

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 o No þ

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 þ No o

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 þ

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

Large accelerated filer þ	Accelerated filer o	Non-accelerated filer o	Smaller reporting company o

(Do not check if a smaller reporting company)

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

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 28, 2007), the aggregate market value of the Common Shares of the Registrant held by non-affiliates of the Registrant was approximately $1,314,500,013. 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 May 23, 2008, there were approximately 33,759,970 Common Shares outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant s Proxy Statement for its Annual Meeting of Shareholders to be held on September 15, 2008 are incorporated by reference into Part III of this Form 10-K.

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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 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 U.S. Securities and Exchange Commission (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 ar 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 operating results for fiscal 2009;
- Our expectations regarding future developments in the markets in which we compete and intend to compete;
- Our anticipated growth strategies;
- Our intention to introduce or seek approval for new products;
- Our ability to continue to meet United States Food and Drug Administration (FDA) and other regulatory requirements;
- Our anticipated outcomes of regulatory reviews;
- Our anticipated outcomes of litigation; and
- Our ability to replace sources of supply without disruption and regulatory delay.

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, product recalls, difficulties with new product development, the introduction of new products by our competitors, changes in the economy, FDA or other regulatory 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.

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ITEM 1. BUSINESS.

Mentor Corporation was incorporated in Minnesota in 1969. Our fiscal year ends on March 31, and references to fiscal 2008, fiscal 2007 or fiscal 2006 refer to the years ended March 31, 2008, 2007 or 2006, respectively.

General

We develop, manufacture, license and market a range of products serving the aesthetic medical market, including plastic and reconstructive surgery. Our products include breast implants for plastic and reconstructive surgery, capital equipment and consumables used for soft tissue aspiration for body contouring (liposuction), and facial rejuvenation products including various types of products for skin restoration. Historically, we operated in three reportable segments: aesthetic and general surgery, surgical urology, and clinical and consumer healthcare. In June 2006, we sold the surgical urology and clinical and consumer healthcare businesses. We currently operate in one business segment aesthetic products.

Principal Products and Markets

Our aesthetic products fall into three general categories: breast aesthetics, body contouring, and other aesthetics which includes facial aesthetics products. These three product lines are considered one segment for financial reporting purposes. Net sales for each of these product categories and the percentage contributions of such net sales to total net sales are as follows:

	Year Ended March 31,					
	2008		2007		2006	
(in thousands)	**Amount**	**%**	Amount	%	Amount	%
Breast aesthetics	**$ 328,027**	**87.9%**	$ 262,556	87.0%	$ 233,189	87.0%
Body contouring	**15,212**	**4.1%**	16,734	5.5%	17,782	6.6%
Other aesthetics, including facial products	**29,969**	**8.0%**	22,684	7.5%	17,301	6.4%
Total	**$ 373,208**	**100.0%**	$ 301,974	100.0%	$ 268,272	100.0%

We develop, produce, and market a broad line of breast implants, including saline-filled implants and silicone gel-filled (MemoryGel and Contour Profile® brand) 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 breast implants incorporate silicone gel with varying degrees of cohesiveness. Additionally, our implants have either a smooth or textured surface and are provided in a variety of sizes and shapes to meet the varying preferences and needs of patients and surgeons.

Breast implants have applications in both cosmetic and reconstructive plastic surgery procedures. These implants are used in augmentation procedures to enhance breast size and shape, correct breast asymmetries and help restore fullness after breast feeding. During reconstruction procedures, breast implants 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 at a later date.

We estimate the size of the markets for our products using external data and management judgment. We believe the worldwide breast aesthetics market to be approximately $800 million to $850 million per year.

We work actively with FDA as we seek approvals of our pre-market approval applications and our biologic license applications, as well as when we carry out our post-approval conditions. We also work with non-U.S. agencies related to these processes. Following are some key dates related to these activities:

- During the third quarter of fiscal 2008, we began enrollment of our botulinum toxin type A Phase IIIb study for the treatment of glabellar rhytides (frown lines). Enrollment was completed in January 2008. In February 2008, we began enrollment for our Phase IIIc study, and enrollment was completed in April 2008. In February 2008, FDA approval was received for Prevelle Silk, a hyaluronic acid dermal filler containing lidocaine that is manufactured by Genzyme Corporation and distributed by us.

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Our MemoryGel breast implants have been approved by FDA subject to post-approval conditions, including a Post-Approval Study (PAS). To date, we have enrolled over 33,000 patients toward the PAS enrollment goal of 42,900 patients. We anticipate concluding enrollment by the end of calendar year 2008.

Our Contour Profile Gel breast implants submission was filed with FDA in September 2006 and is under review by the agency.

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 second-stage operation. All CPX devices utilize our proprietary, self-sealing BufferZone® technology and Centerscope injection port locators.

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 common applications for extremity tissue expanders include the correction of disfigurements such as burns, large scars and congenital deformities.

With respect to body contouring, we market a complete line of liposuction products and disposable supplies. We estimate the worldwide market for body contouring products to be approximately $40 million to $65 million per year.

Our other aesthetics category includes Mentor Solutions and facial aesthetics. The Mentor Solutions group offers software, consulting and business management tools to help plastic surgeons grow their business. In facial aesthetics, we supply dermal filler products and cosmeceutical products that help plastic surgeons and dermatologists treat a variety of skin conditions. We estimate the worldwide market for dermal filler products to be approximately $700 million to $800 million per year. Currently, in the U.S. we sell Prevelle Silk, a hyaluronic acid-based dermal filler with lidocaine that is manufactured by Genzyme and is used for the correction of facial lines and wrinkles. Outside of the U.S., we sell the following dermal filler products: (a) Puragen Plus , our double cross-linked hyaluronic acid-based dermal filler with lidocaine; and (b) Prevelle , a hyaluronic acid-based dermal filler without lidocaine that is manufactured by Genzyme. These products complement each other by offering treatment options for a wide variety of patients looking for wrinkle correction. We continue to pursue FDA approval for Puragen Plus in the U.S. and for Prevelle Silk in certain territories outside of the U.S. In addition, as part of our commercialization agreement with Genzyme, we are pursuing FDA approval of dermal gel extra, a next-generation hyaluronic acid-based dermal filler product.

Our cosmeceutical products are the NIA 24 line of science-based products that are used to improve and restore the healthy appearance of the skin, which we distribute pursuant to an agreement with Niadyne, Inc.

Most of our sales take place in the U.S., and the majority of such sales are not subject to reimbursement by the government or third parties. Economic conditions can adversely affect the sales of our products, as described in the preceding sentence, because the end-users of our products may react to employment levels, energy and fuel costs, interest rates and other factors that can reduce consumer discretionary spending.

We are developing a botulinum toxin type A product utilizing proprietary technology. We estimate the worldwide market for botulinum toxin products to be greater than $1 billion per year, of which approximately 50% relates to therapeutic uses and 50% to cosmetic use. The only therapeutic indication that we are currently conducting clinical trials in is cervical dystonia (torticollis). We have completed our Phase I and Phase II studies for the treatment of glabellar rhytides (frown lines). The Phase III studies are comprised of three separate protocols, two of which were submitted to FDA as Special Protocol Assessments. The first is a single treatment safety and efficacy study, while the second is a repeat treatment safety and efficacy trial. The third study is designed to collect long term safety data over a three-year period. We have completed enrollment in all three of our Phase III studies. Additionally, in early fiscal 2007, we initiated the United States Phase I dose-escalation study focused on the treatment of adult-onset spasmodic torticollis/cervical dystonia. This study is now closed to enrollment.

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Sales and Marketing

We employ a direct sales force domestically for our aesthetic surgery and facial product lines, as well as specialists to support our body contouring product line. The sales force provides product information training, 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, specialized websites, journal advertising, direct mail programs, and a variety of marketing support programs. One of our most successful marketing initiatives in fiscal 2008 has been our Mentor Masters Series, which is an ongoing educational event that allows physicians to visit our manufacturing facility in Dallas, Texas and see first hand how our breast aesthetics products are manufactured. We are currently the only company that manufactures breast implants in the United States. We employ rigorous quality standards carried out by our long-tenured staff. In addition, we support our physicians and their staff through ongoing education at our Mentor Paragon Forum educational events. These educational symposia are hosted around the globe and feature leading experts on the latest developments and techniques in breast aesthetics surgery. In February 2008 we launched a new consumer website under the domain name LoveYourLook.com. This website features unique educational tools and support forums to help consumers educate themselves on procedures and find qualified surgeons in their area. In addition, we recently signed a co-marketing agreement with Le Mystere, a manufacturer of high-end lingerie and bras designed specifically for patients undergoing breast surgery.

We contribute to organizations that provide counseling and education for patients suffering from certain conditions (such as breast cancer survivors or breast reconstruction support organizations), and we provide our physicians with educational materials related to our products for use with their patients.

International Operations

We distribute most of our product lines to markets outside of the U.S., principally to Canada, Europe, Central and South America, and the Pacific Rim. Products are sold through our direct international sales offices in Canada, France, the United Kingdom, Germany, Spain, Italy and Australia, as well as through independent distributors in other countries. Total foreign net sales for continuing operations, (which are made through distributors and direct international sales offices) were $116.0 million, $84.2 million and $75.5 million, in fiscal 2008, 2007 and 2006, respectively. Other than sales made through our international sales offices, which are denominated in the local currency of the respective sales office, international sales are generally made in U.S. dollars.

In addition, we manufacture breast implants in the Netherlands, France and Mauritius. During fiscal 2007, we recorded a $2.6 million impairment charge related to our decision to close our manufacturing and research facility in Scotland. Total long-lived assets, excluding those related to discontinued operations, located in foreign countries were $86.1 million and $21.5 million as of March 31, 2008 and 2007, respectively.

On July 2, 2007, we purchased all of the outstanding shares of Perouse Plastie SAS (Perouse), a medical device company based in Bornel, France. Perouse is a manufacturer and distributor of silicone gel breast implants for a number of established and emerging international markets and sells its products under the Perouse Plastie Perthese® brand. Perouse s primary manufacturing facility is located in France and a second facility is located in Mauritius. For additional information regarding our international operations, see Note U Segment Information for Continuing Operations of the Notes to Consolidated Financial Statements.

Competition

We believe that we are one of the leading worldwide suppliers of cosmetic and reconstructive surgery products. In the domestic breast implant market, we compete primarily with one other company, Allergan, Inc. (Allergan), which acquired Inamed Corporation, our largest competitor in the U.S. in terms of our breast aesthetics products, in March 2006. As a result of Allergan s acquisition of Inamed, we now compete with a much larger company. The principal competitive factors in this market are product performance and quality, range of styles and sizes, proprietary design, warranty programs, customer service and, in certain instances, price. In addition to current competition from Allergan, there is a strong possibility of additional competition from new entrants into the U.S. market. Several companies have clinical studies underway to receive FDA approval to market their own silicone- and saline-filled breast implants. Outside the U.S., we compete with Allergan and various smaller competitors. Notwithstanding relative company sizes, some of the smaller competitors have strong positions in their home markets, which intensifies the challenges associated with maintaining and growing our international business.

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In facial aesthetics, we are a new entrant in the worldwide market and consequently are not a leading competitor. The commercialization agreement reached with Genzyme for hyaluronic acid dermal fillers is expected to provide significant future benefit as we access their manufacturing and research and development expertise in hyaluronic acid technology. Many competitors, both domestically and internationally, exist in the facial aesthetics market; some of these competitors have hyaluronic acid-based products similar to our own, while others have different products and technologies.

Several companies are currently selling botulinum toxin products for facial aesthetics as well as multiple therapeutic indications in global markets outside the United States. Inside the United States, Allergan and one other company distribute the only approved botulinum toxin products, although several other companies have botulinum toxin products in clinical trials. Those companies are seeking additional indications and other companies are pursuing regulatory approval.

Government Regulations

General

Our manufacturing processes and facilities are subject to continuing review by the FDA and various state and international 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. Future interpretations made by these agencies could adversely affect us. Failure to comply with these agencies regulatory requirements may result in enforcement action, 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, the Federal Trade Commission (FTC), other federal and state agencies in the U.S., and by comparable agencies internationally. A 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 U.S. Department of Homeland Security regulation and oversight from time to time and could be considered for restricted entry into the U.S. 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.

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

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U.S. 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 substantial equivalence to a legally marketed device prior to marketing devices for which the FDA requires pre-market approval or clearance; (iii) require laboratory and/or animal test data to be submitted to the FDA prior to testing of devices in humans; (iv) establish Good Manufacturing Practices (GMPs), referred to as Quality System Regulation (QSR), that must be followed in device manufacture; (v) permit detailed inspections of device manufacturing facilities for compliance with QSR; (vi) require compliance with certain labeling requirements; (vii) require reporting of certain adverse events, device malfunctions, and other post-market information to the FDA; and (viii) prohibit device exports that do not meet certain requirements. The FDA also regulates marketing and promotional activities by device companies. Essentially, all of our currently marketed products are medical devices and, therefore, are subject to regulation by the FDA in the U.S. and analogous governmental agencies in countries outside the U.S. to which we export our products. We expect other products in development and under regulatory review, such as Puragen Plus , to be subject to FDA regulation as medical devices.

The FDCA established complex procedures for FDA regulation of devices. Devices are placed in three classes: Class I (general controls, such as establishment registration, device listing, and labeling requirements); Class II (special controls, such as industry standards or FDA guidance documents, 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 November 2006, the FDA approved our PMA application for our MemoryGel round silicone gel-filled breast implants for breast augmentation, reconstruction and revision. Pursuant to conditions of approval set forth in the FDA s approval letter, we are required to conduct a large, post-approval study following 42,900 women for 10 years after receiving breast implants. The FDA often requires post-approval studies to answer important questions that can only be answered once a product is in broader use, such as the incidence of rare adverse events. Accordingly, the post-approval studies for our MemoryGel silicone gel-filled breast implants are designed to gather information about the implants and to provide this data to the FDA. We are incurring, and expect to continue to incur, additional expenses in connection with the conduct of this study, which could be substantial.

In September 2006, we submitted the completed modular PMA application to the FDA for our Contour Profile® silicone gel-filled breast implant products (CPG®). The application is currently under review.

Regulation of Biologics

Our botulinum toxin product under development is regulated by the FDA as a biological product under the Public Health Service Act and is 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 biological product, 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 several other agencies in the U.S., such as the Department of Health and Human Services and the Centers for Disease Control, due to the nature of the biological agent used to manufacture our botulinum toxin product (Clostridium botulinum type A). The product is still in the development phase. Failure to comply with the regulations and requirements of these various agencies could affect our ability to manufacture and commercialize the product and may have a significant negative future impact on sales and results of operations.

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, most notably in Canada

and the European Union (EU).
In October 2006, Health Canada approved Medical Device Licenses for our round and Contour Profile Gel silicone gel-filled breast implants.

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A medical device may only be marketed in the EU if it complies with the Medical Devices Directive (93/42/EEC) (MDD), the Active Implantable Medical Devices Directive (90/385/EEC) (AIMDD) or the In Vitro Diagnostic Device Directive (98/97/EC) (IVDD), as appropriate, 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, AIMDD or the IVDD 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.

Our botulinum toxin product, which is a biologic, 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 three 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; the Mutual Recognition Procedure (MRP) whereby a marketing authorization is granted by one national authority and is subsequently recognized by the authorities of the other member states in which we intend to supply the products; or the decentralized procedure, whereby an application for a marketing authorization is submitted simultaneously to the 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 or the decentralized procedure 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 results of operations 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. Violations of environmental health and safety laws could 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.

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Medicare, Medicaid and Third-Party Reimbursement

Health care providers that purchase medical devices, such as our products, sometimes 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. In addition, if our botulinum toxin is approved for therapeutic indications, it will be subject to these coverage and reimbursement policies.

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 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.

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Medicare Outpatient Hospital Setting

CMS implemented the hospital Outpatient Prospective Payment System, or OPPS, effective August 2000. OPPS is the current payment methodology for hospital outpatient services, among others. Services paid under the OPPS are classified into groups called Ambulatory Payment Classifications, or APCs. 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. OPPS 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 OPPS through the payment of additional outlier payments and transitional pass-through payments to outpatient providers reimbursed through OPPS 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. Our products do not currently qualify for pass-through payments.

CMS proposes and, after consideration of public comment, implements annual changes to OPPS and payment rates for the following calendar year. The OPPS 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, which may impact hospital purchasing decisions.

We cannot predict the final effect that any change in OPPS regulations, including future annual updates, will have on our customers or sales. Any such effect, however, could be negative if APC groupings become less advantageous, reimbursement allowables decline, or if the OPPS 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 constraints. Changes to any state s 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 sales and results of operations.

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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. 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

Although we do not submit claims for payment directly to the federal government, we may become subject to state and federal laws that govern the submission of claims for reimbursement by virtue of the submission of such claims by our customers. 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 and treble damages. 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.

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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. 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.

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, or authorize 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 on obtaining FDA and other regulatory approval of certain products and processes, and we maintain the highest quality standards of existing products. During fiscal years 2008, 2007 and 2006, we spent a total of $45.0 million, $35.0 million and $29.0 million, respectively, for research and development primarily in support of our silicone gel breast implant regulatory submissions in the United States and Canada, post-approval study costs related to our silicone gel-filled breast implants, laboratory testing and clinical studies for our hyaluronic acid-based dermal fillers and our botulinum toxin development projects.

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, breast implant manufacturing and design technologies, botulinum toxin, hyaluronic acid dermal fillers, 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 breast implants and certain components used for those implants. 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 2008.

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Our saline-filled and MemoryGel breast implants and other products are available for sale in the U.S. under FDA approvals and/or clearances. 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.

We depend on Genzyme for the supply of Prevelle Silk, which is a hyaluronic acid dermal filler product with lidocaine we distribute in the U.S. and Prevelle , a hyaluronic acid dermal filler we distribute internationally; Tutogen Medical, Inc. for the supply of NeoForm , a human tissue product used in breast reconstruction procedures; and Niadyne, Inc. for the supply of NIA-24, a line of science-based, cosmeceutical products used to improve and restore the healthy appearance of the skin. We also rely on a contract manufacturing facility to perform fill/finish operations for our botulinum toxin. This facility must comply with all applicable regulations and must undergo successful FDA inspection in order to complete our BLA.

Seasonality

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

Working Capital

We believe 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.

We believe 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 we believe they are 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, 2008, we employed approximately 1,190 people, of whom 650 were in manufacturing, 288 in sales and marketing, 101 in research and development and 151 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. Total consideration was $463 million, including $456 million in cash and $7 million consisting of an indemnification by Coloplast to Mentor related to certain foreign tax credits that arose from the transaction. On June 2, 2006, we completed this sale to Coloplast and the post-closing adjustment of $2.7 million was paid by us to Coloplast in the fourth quarter of fiscal 2007. 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. As of March 31, 2008, all but $3.9 million of the initial $10 million had been released from escrow.

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 $2 million.

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Operations associated with the Urology Business have been classified as income (loss) 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 recorded a net gain on the sale of our Urology Business in the first quarter of fiscal 2007. As a result of this sale, we are able to focus on the aesthetic market. We intend to leverage our traditional strengths in plastic surgery and grow our market presence in cosmetic dermatology with products for both surgical and non-surgical procedures.

Executive Officers of the Registrant

Our executive officers as of May 23, 2008 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	49	President and Chief Executive Officer
Edward S. Northup	59	Vice President, Chief Operating Officer
Michael O Neill	48	Vice President, Chief Financial Officer and Treasurer
Joseph A. Newcomb	57	Vice President, General Counsel and Secretary