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

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

FORM 10-K

(Mark One)

x 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

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)

Title of Each Class	Name of Each Exchange on Which Registered
Common Shares	**New York Stock Exchange**

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 x 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 x

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 x 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 o

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 x Accelerated filer o Non-accelerated filer o

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

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.

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

TABLE OF CONTENTS

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:

	Year Ended March 31,					
	2006		2005		2004	
(in thousands)	**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.

In fiscal 2005, we established two new business lines in the aesthetics arena, which we categorize under "other aesthtics": 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.

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.

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

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,™ 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 OPPS, effective July 1, 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 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. OPPS may cause providers of outpatient services with costs above the payment rate to incur losses on such services provided to Medicare beneficiaries.

12

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.

Annually CMS proposes, and after consideration of public comment, implements 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 and 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 our revenues. 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 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.

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.