

MENTOR CORP /MN/  
Form 10-K  
June 28, 2002

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended March 31, 2002  
or

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

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

Commission File No. 0-7955

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

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

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

Securities registered pursuant to Section 12(b) of the Act: NONE

Securities registered pursuant to Section 12(g) of the Act:

Common Shares, par value \$.10 per share

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes

No  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 the 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

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Based on the closing sale price on the Nasdaq National Market on June 26, 2002, the aggregate market value of the voting stock of the Registrant held by non-affiliates of the Registrant was approximately \$819,826,000. For purposes of this calculation, shares held by each 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 26, 2002 there were approximately 23,608,813 Common Shares outstanding.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2002 Annual Meeting of Shareholders are incorporated by reference in Part III in this Report on Form 10-K.

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#### TABLE OF CONTENTS

<u>ITEM</u>	<u>PART I</u>	<u>PAGE</u>
1.	Business	4
	General	4
	Principal Products and Markets	5
	Sales by Principal Product Lines	6
	Marketing	7
	International Operations	7
	Competition	7
	Government Regulations	8
	Medicare, Medicaid and Third Party Reimbursement	10
	Product Development	13
	Patents and Licenses	13
	Raw Material Supply	14
	Employees	14
	Executive Officers of the Registrant	15
2.	Properties	16

3.	Legal Proceedings	16
4.	Submission of Matters to a Vote of Security Holders	17
<u>PART II</u>		
5.	Market for the Registrant's Common Equity and Related Shareholder Matters	17
6.	Selected Financial Data	18
7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	19
7A.	Quantitative and Qualitative Disclosures About Market Risk	29
8.	Financial Statements and Supplementary Data	29
9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	29
<u>PART III</u>		
10.	Directors and Executive Officers of the Registrant	30
11.	Executive Compensation	30
12.	Security Ownership of Certain Beneficial Owners and Management	30
13.	Certain Relationships and Related Transactions	30
<u>PART IV</u>		
14.	Exhibits, Financial Statement Schedules and Reports on Form 8-K	31
	Report of Independent Auditors	32
	Consolidated Financial Statements	33
	Signatures	57
	Exhibit Index	58

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## PART I

This Annual Report on Form 10-K filed on behalf of Mentor Corporation ("Mentor" or the "Company"), including information incorporated herein by reference, contains certain forward-looking statements that involve risk and uncertainty. Such forward-looking statements are characterized by future or conditional verbs and include statements regarding new and existing products, technologies and opportunities, market and industry segment growth and demand and acceptance of new and existing products. Such statements are only predictions and our actual results may differ materially from those anticipated in these forward-looking statements. Factors that may cause such differences include, but are not limited to, increased competition, changes in product demand, changes in market acceptance, new

product development, United States Food and Drug Administration, "FDA", approval, delay, or rejection of new or existing products, changes in government regulation, supply of raw materials, changes in reimbursement practices, adverse results of litigation and other risks identified in this Annual Report or in other documents filed by the Company with the Securities and Exchange Commission. Specific attention should be directed to the sections entitled "Government Regulation," "Legal Proceedings," and "Factors that May Affect Future Results of Operations." The Company assumes no obligation to update forward-looking statements as circumstances change.

## **ITEM 1. BUSINESS.**

### General

The Company develops, manufactures and markets a broad range of products for the medical specialties of aesthetic and general surgery (plastic and reconstructive surgery) and urology. Aesthetic and general surgery products include surgically implantable prostheses for plastic and reconstructive surgery and capital equipment used in soft tissue aspiration. Surgical urology products include surgically implantable prostheses for the treatment of impotence and brachytherapy seeds for the treatment of prostate cancer. Clinical and consumer healthcare products include catheters and other products for the management of urinary incontinence and retention.

During fiscal 2000, the Company substantially completed the divestiture of its ophthalmology business. All sales, expenses, gains on assets sales, and other financial information for the ophthalmology business are reported, net, as a single line on the Company's financial statements.

Effective January 19, 2001, Mentor acquired the assets of South Bay Medical, LLC, a development-stage company focused on the development of a new technology for a computer-based workstation and automated cartridge-based needle loading system for use in brachytherapy procedures.

Effective February 9, 2001, Mentor acquired Porges S.A., a subsidiary of Sanofi-Synthelabo headquartered in Paris with manufacturing facilities in Sarlat, France. Porges holds a leading market share for urological products in France and has strong market position throughout Europe.

Effective December 31, 2001, the Company acquired the remaining 51% of the shares of Byron Medical, Inc. The Company now owns 100% of the shares. Byron Medical is located in Tucson, Arizona and specializes in the distribution of liposuction equipment and supplies.

Effective December 2001, the Company entered into several agreements with ProSurg, Inc. to acquire certain patent rights, and to obtain a source of supply of a bio-absorbable co-polymer product to be used in the surgical treatment of incontinence. The Company introduced the new product, Sabre™ in June 2002.

Mentor Corporation was incorporated in Minnesota in 1969.

### Principal Products and Markets

#### Aesthetic and General Surgery Products

The Company produces a broad line of mammary prostheses, including saline-filled implants and silicone gel-filled implants. In fiscal 2002, approximately 85% of aesthetic and general surgery revenues were sales of mammary prostheses. Saline-filled breast implants accounted for approximately 67% of mammary prostheses sold in fiscal 2002.

Mammary prostheses have applications in both cosmetic and reconstructive plastic surgery procedures. These prostheses are used in cosmetic augmentation procedures to enhance breast size and shape. In the reconstruction procedure market, mammary prostheses are utilized as a surgical solution to reform the breast following a

mastectomy. Breast reconstruction is a surgical option for many women following mastectomy either at the time of surgery or a later date.

The Company also offers a line of tissue expanders. Tissue expansion is a technique for growing additional tissue for reconstruction and skin graft procedures. Some of the major applications of tissue expansion developed to date include post-mastectomy breast reconstruction and the improvement of disfigurements such as burns, large scars and congenital deformities.

In September 1997, the Company began marketing the Contour Genesis<sup>®</sup> System, an ultrasound-assisted product used for the aspiration of soft tissues in general surgery and cosmetic surgery applications. The Company has completed clinical trials using the Contour Genesis<sup>®</sup> System in order to expand the labeling of the product to include ultrasonic-assisted liposuction and received approval from the Food and Drug Administration ("FDA") to expand the labeling in October 2001. The December 2001 acquisition of Byron Medical, Inc. expanded the Company's offering of liposuction products to include traditional and power assisted product offerings. Subsequently, the Company acquired the assets of LySonix, Inc., a former competitor in ultrasonic liposuction equipment and supplies. As a result of these two acquisitions, the Company is positioned as a broad line supplier to the entire body contouring (liposuction) market.

### Surgical Urology Products

The Company's surgical urology products fall into three general categories: erectile dysfunction products, urinary care and pelvic floor products, and cancer treatment products.

#### Erectile Dysfunction Products

. The Company's erectile dysfunction products consist of a line of penile implants for the treatment of male sexual impotence. Penile prostheses are implanted in men who cannot achieve a natural erection of sufficient rigidity for sexual intercourse. Penile implants have become the standard of care for men who have not responded to less invasive therapies, the best known of which is Pfizer's Viagra<sup>®</sup>. In order to respond to various physician and patient preferences, the Company manufactures several types of penile prostheses, including a hydraulic inflatable device and a malleable prosthesis. Late in fiscal year 2000, the Company introduced a major improvement to its Alpha 1 inflatable device, the Lockout<sup>®</sup> valve. The Lockout valve was designed to prevent auto-inflation, a potential complication in this type of treatment. In May 2002, the Company received Canadian and Conformance Europeene, "CE" approval for the sale and marketing of penile implants utilizing a new Resist<sup>™</sup> coating designed to reduce bacterial adherence.

#### Urinary Care and Pelvic Floor Products

. The Company markets the Suspend<sup>®</sup> Sling for use in pubovaginal sling and pelvic floor reconstruction procedures. Pubovaginal sling procedures provide relief for women suffering from stress incontinence. Pelvic floor reconstruction procedures utilizing Suspend tissue are commonly used to treat women suffering from all types of vaginal prolapse. In February 2002, the Company introduced Axis<sup>™</sup>, a dermal based tissue, which like Suspend is treated using the patented Tutoplast<sup>®</sup> process to provide the surgeon with additional tissue choices. In March 2002, the Company announced the introduction of Sabre<sup>™</sup> a bio-absorbable synthetic co-polymer sling to be used in the surgical treatment of incontinence.

#### Cancer Treatment Products

. The Company serves as the marketing partner in a strategic alliance focused on the treatment of prostate cancer. The alliance is with North American Scientific, Inc. ("NASI") a producer of brachytherapy seeds for the treatment of prostate cancer. NASI manufactures and ships I<sup>®</sup> I-125 and Pd-Gold<sup>®</sup> Pd-103 brachytherapy seeds, while the Company performs all of the sales and marketing functions. In January 2001, the Company announced the acquisition of South Bay Medical, LLC and its new technology for a computer-based workstation and automated cartridge-based needle loading system for use in brachytherapy procedures. Early in fiscal year 2002, the Company submitted a 510(k) application to the FDA for approval to market the system. The FDA had requested additional information regarding the application. The Company has responded to all of the FDA's requests and believes the FDA now has all the necessary information to grant approval. The Company expects to receive approval from the FDA in the second quarter of fiscal 2003 and to begin sales of the workstation immediately thereafter. However, there is no guarantee that the FDA will grant the approvals necessary to allow marketing of the workstation in the United States. In April 2002, the Company received the necessary approvals from the Canadian Therapeutic Products Directorate to market and sell the

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Isoloader™ workstation and needle loading system in Canada. The Company expects to begin sales of the Isoloader workstation into the Canadian market in the second quarter of fiscal 2003.

### Clinical and Consumer Healthcare Products

The Company markets a line of male external catheters that help men manage their incontinence and a line of intermittent self-catheters for men, women and children who suffer from urinary retention. These products are disposable and are used in homes, hospitals and rehabilitation and extended care facilities.

In February 2001, the Company announced the acquisition of Porges S.A., a French company specializing in urological disposables, including diagnostic tools, and various devices for surgery and postoperative follow-up. The Company introduced the first of these products into the U.S. market in fiscal 2002.

The Company also markets a variety of other disposable products used in the management of urinary incontinence and cancer. These include leg bags and urine collection systems, organic odor eliminators, and moisturizing skin creams and ointments. In April 2001, the Company began to distribute the BTA *Stat*

® point-of-care bladder cancer screening test manufactured by Polymedco Inc. under an exclusive supply and distribution agreement.

The Company introduced the Self-Cath Plus™, a lubricious coated intermittent catheter along with a closed system sterile intermittent catheter in fiscal 2002.

### Sales by Principal Product Lines

The following table shows the net sales attributable to each of the Company's principal product lines and the percentage contributions of such sales to total net sales for the periods indicated.

	Year Ended March 31,					
	2002		2001		2000	
(in thousands)	Amount	%	Amount	%	Amount	%
Aesthetic and General Surgery	\$163,091	51%	\$157,122	59%	\$150,334	60%
Surgical Urology Products	94,341	29	62,264	23	52,794	21
Clinical and Consumer Healthcare	63,630	20	49,508	18	46,217	19
	\$321,062	100%	\$268,894	100%	\$249,345	100%

For additional information regarding the Company's revenues, operating profits and identifiable assets attributable to the Company's business segments as well as domestic and foreign operations, see Note O of the "Notes to Consolidated Financial Statements."

### Marketing

The Company employs specialized domestic sales forces for aesthetic surgery, surgical urology and disposable healthcare product lines. Each sales force provides product information or specific data support and related services to

physicians, nurses and other health care professionals. The Company also markets certain products, particularly its disposable incontinence products, through a domestic network of independent hospital supply dealers and healthcare distributors, and increasingly through retail pharmacies.

The Company promotes its products through radio, magazine and journal advertising, direct mail programs, and participation in, and sponsorship of, medical conferences and educational seminars. The Company also participates in support organizations that provide counseling and education for persons suffering from specific disease states, and provides patient education materials for some of its products to physicians for use with their patients.

### International Operations

The Company exports most of its products lines, principally to Canada and Western Europe. Products are sold to both independent distributors as well as through the Company's direct international sales offices in Canada, the United Kingdom, Germany, France, Japan, Benelux, Australia, Spain, Portugal and Italy. Other than sales made through the Company's international sales offices, export sales have been made in United States dollars and currency fluctuations have not significantly affected operating earnings. The Company generally does not use derivative instruments to hedge its foreign currency transactions. In fiscal 2002, sales from the direct international offices accounted for 28% of total Company sales.

In addition, the Company manufactures mammary implants in Leiden, the Netherlands, and through its acquisition of Porges, has manufacturing facilities in Sarlat, France where urological disposables distributed throughout Europe are manufactured.

### Competition

The Company believes it is one of the leading suppliers in the United States of penile implants, cosmetic and reconstructive surgery products, and disposable catheter products. This belief is based upon information developed internally, public information sources, and information from independent research studies of market share.

The Company competes primarily with one other company in the domestic breast implant market, McGhan Medical Corporation, a subsidiary of INAMED, Inc. The primary competitive factors currently are product performance and quality, range of styles and sizes, proprietary design, customer service and in certain instances, price.

The Company competes with only one other company in the inflatable penile implant market, American Medical Systems, Inc. Several companies sell competing malleable penile implants. The primary competitive factors are product performance and reliability, ease of implantation and customer service. The Company believes that by providing several types of implants that emphasize high performance and reliability, it can successfully respond to various physician and patient preferences.

The Company competes with many other companies providing brachytherapy seeds for the treatment of prostate cancer, including Amersham Health Care, C.R. Bard, Inc., Theragenics Corporation and others. The primary competitive factors in this market are technologies that support efficient preparation and implantation of radioactive sources through improved product delivery, product offering and consistent quality. The Company believes that it has the second largest market share for Iodine seeds, as well as for Palladium seeds, and that its recent acquisition of South Bay Medical's automated workstation, Isoloader™, will provide the Company with a strong competitive advantage when it is approved for use in the United States by the FDA. In April 2002, the Company received the necessary approvals to market and sell the Isoloader™ workstation and needle loading system in Canada from the Canadian Therapeutic Products Directorate.

By superior design and active marketing of catheters and other disposable incontinence products, the Company has been able to compete successfully against larger companies in this market. C.R. Bard, Inc., Hollister, Inc., Kendall (a

division of Tyco HealthCare), and Coloplast Corporation are the dominant competitors in the market. As with many of its other product lines, the Company competes primarily on the basis of design and performance, and by providing product orientation, support and related services to health care professionals and consumers. The fiscal 2001 Porges S.A. acquisition provided the Company a dominant position in the European market and the Company intends to introduce several of Porges' products into the U.S. market.

### Government Regulations

#### General

As a manufacturer of medical devices, the Company's manufacturing processes and facilities are subject to continuing review by the FDA and various state and international agencies. These agencies inspect the Company and its facilities from time to time to determine whether the Company is in compliance with various regulations relating to manufacturing practices and other requirements. The FDA has the power to prevent or limit further marketing of products based upon the results of these inspections. These regulations depend heavily on administrative interpretation by the various agencies. There can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect the Company. A determination that the Company is in violation of such regulations could lead to imposition of various penalties, including the issuance of warning letters, injunctive relief (whether by adverse court ruling or by consent), product recalls, civil penalties, product seizures, or criminal prosecution.

#### Medical Device Amendments of 1976

Under the "Medical Device Amendments of 1976" as amended ("the '76 Amendments"), the FDA has the authority to adopt regulations that: (i) set standards for medical devices; (ii) require proof of safety and effectiveness prior to marketing devices which the FDA believes require pre-market clearance; (iii) require test data be submitted to the FDA prior to clinical evaluation in individuals; (iv) permit detailed inspections of device manufacturing facilities; (v) establish "good manufacturing practices" ("GMPs") that must be followed in device manufacture; (vi) require reporting of certain adverse events and device malfunctions to the FDA; and (vii) prohibit device exports that do not meet certain requirements. The FDA also can regulate promotional activities by device companies. All of the Company's products are medical devices or products and are therefore subject to FDA regulation.

The '76 Amendments establish 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 the FDA clearance in addition to general controls), and Class III (pre-market approval application ("PMAA") before commercial marketing). Class III devices are the most extensively regulated. Class III devices require each manufacturer to submit to the FDA a PMAA that includes information on the safety and effectiveness of the device. The majority of the Company's aesthetic surgery and urology implants are in Class III, while most of its disposable incontinence products are in Classes I and II.

In 1991, the Company submitted a PMAA for its 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. The FDA adopted 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 purposes on the basis of a public health need. Since 1993, women have been required to enroll in a clinical study 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. The Company continues to ship these products under the terms of this clinical study.



In 1993, the FDA published proposed guidelines for PMAAs on the Company's hydraulic inflatable penile prostheses and saline-filled breast implants. For saline implants, the Company submitted all the required data and on May 10, 2000, the FDA approved the Company's PMAA. In conjunction with the review of data, the FDA inspected the Company's manufacturing facility in Irving, Texas and indicated the facility was in substantial compliance with the applicable regulations. In addition, the Company submitted all required data for the PMAA for its penile implants, and received FDA approval for the Company's penile implants July 14, 2000.

The Company has 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 in the formats required by the FDA. The process of obtaining marketing clearance and approvals from the FDA for new products and existing products can be time-consuming and expensive, and there is no assurance that such clearances or approvals will be granted. The Company 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 the Company's ability to commercialize additional products or additional applications for existing products.

#### Additional Regulations

As a manufacturer of medical devices, the Company's manufacturing processes and facilities are subject to regulation and review by international regulatory agencies for products sold internationally. The Company has obtained a Conformance Europeene, "CE" mark for its products sold in Europe by demonstrating compliance with the ISO 9001, EN46001 and ISO13485 international quality system standards. Medical device laws and regulations are also in effect in some of the other countries to which the Company exports its products. These range from comprehensive device approval requirements for some or all of the Company's medical device products to requests for product data or certifications. Failure to comply with these international regulatory standards and requirements could affect the Company's ability to market and sell its products in these markets and have a significant negative impact on sales and results of operations.

#### Texas Facility Review

In May 1998, the Company entered into a voluntary consent decree with the FDA, under which the Company agreed, among other things, to complete certain re-validations of the manufacturing processes in agreed upon timeframes that were identified during an FDA inspection.

The consent decree required the Company to hire expert consultants to assist in strengthening the Company's compliance program and related processes. In July 1998, the consultant reported to Mentor management and the FDA that, except for the outstanding re-validations, there were no significant areas of GMP non-compliance. The expert consultant reviewed the re-validations and reported to management and to the FDA that all re-validation projects had been completed within the agreed timeframes.

Additionally, under the terms of the consent decree, a separate expert consultant is required to conduct annual inspections of the Texas facility and issue a report annually to the FDA. The expert consultant has conducted the required annual comprehensive GMP inspections. In each of the annual inspections, 1999 to 2002, the expert consultant has found the Texas facility to be in substantial compliance with FDA good manufacturing practice regulations.

During the period May 1-10, 2000, the FDA conducted an inspection at the Texas facility to assess the procedures under which saline breast implants are manufactured. The inspection was conducted in conjunction with the FDA's final decision on Mentor's saline breast implant PMAA. The inspection resulted in the issuance of an FD483 (form used to report FDA inspection findings) with one observation related to validation of a computer system, which the Company addressed. Mentor's saline breast implant PMAA was subsequently approved.

Between the period April 16-23, 2001, the FDA conducted an inspection at the Texas facility. The inspection was a follow-up inspection related to Mentor's saline breast implant PMAA and the previous inspection. The inspection resulted in the issuance of an FD483 with two observations, one related to a manufacturing process and one related to computer software. Mentor has responded to the FDA on both observations.

In February 2002, the FDA performed a comprehensive GMP/QSR (Good Manufacturing Practice/Quality System Requirements) inspection of the Texas facility. This inspection covered all aspects of the Texas quality systems for gel and saline breast implants and tissue expanders. The inspection resulted in the issuance of an FD483 with three observations: one related to the manufacturing shell dipping process, one related to complaint analysis and one related to gowning practices. The Company has addressed each of these issues.

The Company believes that it will continue to meet the requirements of the consent decree, although there can be no assurance that it can do so. In addition, although the expert consultants have expressed their opinion as to the satisfactory completion of consent decree requirements, FDA inspectors during some future inspections may reach a different conclusion. Should the Company fail to continue to comply with the conditions of the consent decree, under its terms the FDA is allowed to order the Company to stop manufacturing or distributing the breast implants, order a recall or take other corrective actions. The Company may also be subject to penalties of \$10,000 per day until compliance is achieved.

If the Company maintains continuous compliance with the terms of the consent decree for a period of five years after the completion of the re-validations, the Company can petition the courts to remove the consent decree without opposition from the government.

#### Environmental Regulation

The Company is also subject to regulations by the United States Environmental Protection Agency and in certain states, primarily Texas, the Company is subject to regulation by the local Air Pollution Control District as a result of some of the chemicals used in its manufacturing processes. Failure to comply with these regulations and requirements could affect the Company's ability to manufacture its products, and have a significant negative impact on sales and results of operations.

#### Medicare, Medicaid and Third Party Reimbursement

Healthcare providers that purchase medical devices, such as the Company's products, generally rely on third-party payers, including the Medicare and Medicaid programs and private payers, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the products. The Company's products are sold principally to hospitals, physicians, home healthcare suppliers, and others that receive reimbursement for the products and services they provide from these third-party payers. The Company estimates that as much as 40% or more of its product sales could be reimbursed by third-party payers. As a result, demand for the Company's products is dependent in part on the coverage and reimbursement policies of these payers. The manner in which reimbursement is sought and obtained for any of the Company's products varies based upon the type of payer involved and the setting in which the product is furnished and utilized by patients.

Discussed below are certain factors, which could have a significant impact on the future operations and financial condition of the Company. It is difficult to predict the effect of these factors on the operations of the Company; however, the factors described could have a negative impact on such operations and such effect could be material.

#### Medicare

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: Part A which covers inpatient services, home healthcare and hospice care; Part B which covers physician services, other healthcare professional services and outpatient services; and Part C or Medicare+Choice which is a program for managed care plans.

The Medicare program has established guidelines for the coverage and reimbursement of certain equipment, supplies and support services. In general, in order to be reimbursed by Medicare, a healthcare 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 the amount of Medicare reimbursement for the Company's products varies based upon, among other things, the setting in which a Medicare beneficiary received healthcare items and services. Any changes in federal legislation, regulations and policy affecting Medicare coverage and reimbursement relative to the Company's products could have a material effect on the Company's performance. As discussed in greater detail below, the Balanced Budget Act of 1997 ("BBA"), the Balanced Budget Refinement Act of 1999 ("BBRA") and the Benefits Improvement and Protection Act of 2000 ("BIPA") also have impacted Medicare reimbursement for the Company's products.

#### In-Patient Hospital Setting

With the establishment of the prospective payment system in 1983, acute care hospitals are generally reimbursed by Medicare for inpatient operating costs based upon prospectively determined rates. Under the Prospective Payment System ("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 the Company's products. Rather, reimbursement for these costs is deemed to be included within the DRG-based payments made to hospitals for the treatment of Medicare-eligible inpatients that utilize the products. Since 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 the Company, that will reduce the length of inpatient stays, decrease labor or otherwise lower their costs. The Company's 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.

#### Outpatient Hospital Setting

Pursuant to the BBA, CMS implemented the hospital Outpatient Prospective Payment System ("OPPS") effective July 1, 2000. OPPS is the current payment methodology for hospital outpatient services, certain Part B services furnished to hospital inpatients who have no Part A coverage and partial hospitalization services furnished by community mental health centers. All services paid under the OPPS are classified into groups called Ambulatory Payment Classifications ("APC"). Services in each APC are similar clinically and in terms of the resources they require. Depending on the services provided, hospitals may be paid for more than one APC for a patient encounter. 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 BBRA 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 these cost for these items into the base APC group.

The qualification of a device for transitional pass-through payments is temporary. Most of the categories established under the pass-through system will expire on January 1, 2003. At that time, APC payment rates will be adjusted to reflect the costs of devices (and drugs and biologicals) that received transitional pass-through payments. These adjustments will be based on claims data that reflect the use of codes for transitional pass-through devices, drugs and biologicals in conjunction with the CPT codes for the associated procedures.

The Company cannot predict the final effect that changes in OPSS regulations, its annual updates to the regulation and/or the potential retirement of any of its products from Pass-Through status will have on the company or its customers. Any such effect, however, could be negative due to loss of revenue for some products.

#### Home Setting

The Company's disposable urological products are also provided to Medicare beneficiaries in home care settings. Medicare, under the Part B program, reimburses beneficiaries, or suppliers accepting assignment, for the purchase or rental of covered Durable Medical Equipment ("DME") for use in the beneficiary's home or a home for the aged (as opposed to use in a hospital or skilled nursing facility setting). As long as the Medicare Part B coverage criteria are met, certain of the Company's products are reimbursed in the home setting, and reimbursed pursuant to a fee schedule payment methodology.

The BBA, as amended by the BBRA and BIPA, provides for the implementation of Home Health Prospective Payment System beginning October 1, 2000. Under Home Health PPS, most of the services which a Medicare patient receives under a plan of care, will be covered by a single payment received by the home health agency for each 60-day episode of care. After a physician prescribes a home health plan of care, the home health agency assesses the patient's condition and likely skilled nursing care, therapy, and certain other service needs, at the beginning of each episode of care. Home Health Resource Groups ("HHRG"), are used to classify patients for purposes of determining payment rates. The amount of the payment will ultimately depend upon the HHRG category of the patient and is subject to a variety of adjustments. Durable medical equipment is excluded from Home Health PPS. However, certain medical supplies currently provided by the Company in a home care environment could be subject to Home Health PPS and the effect of such regulation on future product revenues and results of operations cannot be predicted.

#### 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 the Company's products may affect future revenue negatively if reimbursement amounts are decreased or discontinued.

#### Private Payers

Many third-party private payers, including indemnity insurers, employer group health insurance programs and managed care plans, presently provide coverage for the purchase of the Company's products. The scope of coverage and payment policies varies among third-party private payers. Furthermore, many such payers are investigating or implementing methods for reducing health care costs, such as the establishment of capitated or prospective payment systems. Future changes in reimbursement methods and cost control strategies may limit or discontinue reimbursement for the Company's products and could have a negative effect on future sales and results of operations.

#### Fraud and Abuse Laws

In addition to Medicare coverage and reimbursement limitations, other aspects of the Medicare program may negatively affect the Company. In 1977, Congress adopted the Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, which have been strengthened by subsequent amendments and the creation of the Office of Inspector General ("OIG") to enforce compliance with the statute, as amended (the "Anti-Fraud and Abuse Law"). The Anti-Fraud and Abuse Law prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration in any form as an inducement or reward for either the referral of patients or the arranging for reimbursable services or products. A violation of the statute is a felony and could result in civil penalties, including exclusion from the Medicare or Medicaid program, even if no criminal prosecution is initiated.

HHS (Health and Human Services) has issued regulations from time to time setting forth so-called "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. To date, twenty-one final safe harbors have been developed. However, failure to fall within a safe harbor or with each element of a particular safe harbor does not mean that an arrangement is *per se* in violation of the Anti-Fraud and Abuse Law. 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. Nevertheless, if an arrangement implicates the Anti-Fraud and Abuse Law and full compliance with a safe harbor cannot be achieved, the Company risks greater scrutiny by the OIG and, potentially, civil and/or criminal sanctions. The Company believes its arrangements are in compliance with the federal Anti-Fraud and Abuse Law; however, no absolute assurance can be given that regulatory authorities would not take a contrary position.

#### Product Development

The Company is focused on the development of new products and improvements to existing products. In addition, research and development expense reflects the Company's efforts to obtain FDA approval of certain products and processes and to maintain the highest quality standards of existing products. During fiscal years 2002, 2001 and 2000, the Company spent a total of \$21,806,000, \$19,632,000, and \$16,701,000, respectively, for research and development.

#### Patents and Licenses

It is the Company's policy to protect its intellectual property rights related to its products when and where possible and appropriate. The Company's patents include those relating to its penile prostheses, tissue expanders, combination breast implant and tissue expander, ultrasonic-assisted soft tissue aspiration and disposable catheters. The Company licenses technology under exclusive supplier and licensing arrangements for certain products, including brachytherapy seeds and breast implants.

In those instances where the Company has acquired technology from third parties, it has sought to obtain rights of ownership to the technology through the acquisition of underlying patents or licenses. While the Company believes design, development, regulatory and marketing aspects of the medical device business represent the principal barriers to entry into such business, it also recognizes that its patents and license rights may make it more difficult for its competitors to market products similar to those produced by the Company. Mentor can give no assurance that any of its patent rights, whether issued, subject to license, or in process, will not be circumvented or invalidated. Further, there are numerous existing and pending patents on medical products and biomaterials. There can be no assurance that the Company's existing or planned products do not or will not infringe such rights or that others will not claim such infringement. No assurance can be given that the Company will be able to prevent competitors from challenging the Company's patents or entering markets currently served by the Company.

The Company has an exclusive worldwide distribution agreement with North American Scientific Inc., "NASI", to market and sell radioactive brachytherapy seeds for the treatment of prostate cancer. The products are manufactured by NASI and are marketed and sold by the Company under the names IoGold

® and PdGold®. The agreement expires in 2003; however the Company has a one-time unilateral option to extend the agreement for three years subject to certain performance criteria. The agreement provides that NASI can terminate the Company's exclusivity with respect to any product for which Mentor fails to achieve target market share in certain designated markets, subject to curing provisions whereby exclusivity can be maintained.

NASI has notified the Company that it believes the required target market share has not been achieved with respect to PdGold

® in 2000 and loGold® in 2001. Subject to a review of the performance criteria by both the Company and NASI, this shortfall could result in NASI's ability to terminate the Company's right of exclusivity, subject to the curing provisions in the agreement, or in the Company's loss of the option to extend the exclusive agreement. While the Company believes all performance criteria have been achieved, if NASI terminates the Company's exclusivity on one or both types of brachytherapy seeds, the Company may be subject to additional competition, litigation or an interruption to supply of the product. While the Company believes that additional satisfactory sources of supply exist for similar radioactive seeds for use in brachytherapy treatment of the prostate, there is no assurance that such supply can be obtained without interruption, regulatory delay or on terms satisfactory to the Company.

As a condition of employment, the Company requires each of its new employees to execute an agreement relating to confidential information and patent rights.

#### Raw Material Supply

The Company obtains certain raw materials and components for a number of its products from single suppliers. The Company's sources of supply could be replaced if necessary without undue disruption, but it is possible that the process of qualifying new materials and/or vendors for certain raw materials and components could cause a material interruption in manufacturing or sales. No material interruptions occurred during the last fiscal year.

The Company's inflatable penile prostheses, saline-filled mammary implants, catheters and other products are available for sale under FDA approvals and/or clearances. Gel-filled mammary implants are only available as part of the adjunct clinical study. A change in raw material, components or suppliers for these products may require a new FDA submission, 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 sales and the results of operations.

The Company licenses technology under exclusive supplier and licensing arrangements for certain products. Those products include the following: Tutogen

® processed fascia lata for the Suspend® Sling, and Tutogen® processed dermis for Axis™, both for used in pelvic floor reconstruction, BTA Stat® bladder cancer test, and radioactive sources for its loGold® and PdGold® brachytherapy seeds. In addition, the licensors are sole-source suppliers of these products to the Company. Any interruption in their ability to supply the product to the Company may have an adverse impact on sales and the results of operations.

#### Employees

As of March 31, 2002, the Company employed 1,781 people, of whom 1,086 were in manufacturing, 413 in sales and marketing, 112 in research and development and 170 in finance and administration. There has never been a work stoppage due to labor difficulties, and the Company considers its relations with its employees to be satisfactory.

#### Executive Officers of the Registrant

The executive officers of the Company, as well as their ages as of June 26, 2002, are listed below, followed by brief accounts of their business experience and certain other information.

<u>Name</u>	<u>Age</u>	<u>Position</u>
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Christopher J. Conway	63	President, Chief Executive Officer, Chairman of the Board
Eugene G. Glover	59	Senior Vice President, Advanced Development
Joshua Levine	44	Senior Vice President, Sales and Marketing, Aesthetics Products
Adel Michael	58	Executive Vice President, Chief Financial Officer and Treasurer
Bobby K. Purkait	52	Senior Vice President, Science and Technology
Clarke Scherff	55	Vice President, Regulatory Compliance
Peter Shepard	56	Senior Vice President, Sales and Marketing, Urology Products

Mr. Conway is a founder of the Company and has served as Chairman of the Board since 1969. He served as Chief Executive Officer from 1969 to July 29, 1999. He resumed the positions of Chief Executive Officer and President in September 2000.

Mr. Glover is a founder of the Company and held the position of Vice President, Engineering from 1969 to 1986. In October 2000, he was appointed Senior Vice President, Advanced Development.

Mr. Levine joined the Company in October of 1996 as Vice President Sales, Aesthetic Products. In September of 1998, he was promoted to domestic Vice President Sales and Marketing Aesthetic products. In January 2000, Mr. Levine resigned from the Company to briefly join a start-up practice management organization, The Plastic Surgery Company, ("PSU"), where he was Chief Development Officer. He resigned this position at PSU in September 2000 to rejoin the Company as its Vice President Sales & Marketing. Subsequent to this resignation, PSU filed a voluntary petition for bankruptcy under Chapter 11 of the U.S. Bankruptcy Code in March 2002. In November of 2001, Mr. Levine assumed global responsibilities for all aesthetic sales and marketing activities of the Company and was promoted to Senior Vice President Sales & Marketing in June of 2002.

Mr. Michael joined the Company in April 2000 as Senior Vice President, Chief Financial Officer and Treasurer. He was promoted to Executive Vice President on September 14, 2001. From 1989 to 2000 he was Vice President, Chief Financial Officer of Getz Brothers and Co., Inc., and from 1983 to 1989 he was a Group Controller for the Marmon Group, Inc.

Mr. Purkait joined the Company in February 1986 and has served in various research and development capacities. He was promoted to Vice President Science and Technology in 1988, and Senior Vice President in April 1998. In January 2002, his responsibilities were changed to focus on identifying and assessing the value and feasibility of new technologies.

Mr. Scherff joined the Company in July 1995 as Director of Regulatory Affairs through the acquisition of Optical Radiation Corporation, where he held the position of Group Vice President Quality Assurance/Regulatory Affairs from April 1993 to June 1995. He was promoted to Vice President Quality and Regulatory Assurance in June 1997 and to Vice President of Regulatory Compliance/Compliance Officer in October 2000. From 1980 to 1993, Mr. Scherff held various positions of increasing responsibility for American Hospital Corporation/Baxter Healthcare Corporation, ultimately serving as the Director of Quality Assurance.

Mr. Shepard joined the Company in 1976 as a sales representative. In 1982, he was promoted to Vice President Sales and in 1992 to Vice President Sales and Marketing for the Surgical Urology and Healthcare products. Beginning 1996, he was assigned as Vice President Business Development for the Company. In October 2000, Mr. Shepard resumed the position of Vice President Sales and Marketing for the Surgical Urology and Healthcare product lines. He was

promoted to Senior Vice President Sales and Marketing, Urology and Healthcare products in May 2002.

**ITEM 2. PROPERTIES.**

The Company owns manufacturing, warehouse and office buildings in Minneapolis, Minnesota (161,965 sq. ft.), Sarlat, France (123,800 sq. ft.), Leiden, the Netherlands (64,500 sq. ft.) and manufacturing facilities in Anoka, Minnesota (20,000 sq. ft.). The Company leases additional office, manufacturing and warehouse facilities in Santa Barbara, California (128,000 sq. ft.), Minneapolis, Minnesota (163,000 sq. ft.), Eden Prairie, Minnesota (2,500 sq. ft.), Irving, Texas (134,000 sq. ft.) and Tucson, Arizona (19,500 sq. ft.). The Company has international sales offices located throughout ten countries where it leases office and warehouse space ranging from 1,000 to 37,000 square feet. All leases have terms ranging from 1 to 15 years, renewable on terms the Company considers favorable. For information regarding lease obligations see Note K "Commitments" under "Notes to the Consolidated Financial Statements".

The Aesthetic & General Surgery business segment utilizes the facilities in Irving, Texas, Tucson, Arizona and Leiden, the Netherlands for manufacturing, warehouse and office space. Surgical Urology utilizes the facility in Eden Prairie, Minnesota as well as sharing the Minneapolis, Minnesota and Sarlat, France facilities with the Clinical & Consumer Healthcare segment for manufacturing, warehouse and office space. The Clinical & Consumer Healthcare segment utilizes the facility in Anoka, Minnesota as well as sharing the Minneapolis, Minnesota and Sarlat, France facilities with the Surgical Urology segment for manufacturing, warehouse and office space. The Santa Barbara, California facility as well as the international sales offices serve more than one segment.

The Company believes its facilities are generally suitable and adequate to accommodate its current operations and additional suitable facilities are readily available to accommodate any future expansion as necessary.

**ITEM 3. LEGAL PROCEEDINGS.**

In 1998, the Company learned that the FDA's Office of Criminal Investigations ("OCI") was conducting an investigation involving the Company. The Company understood that the investigation was dormant until April 2000 when OCI issued a letter requesting that the Company provide OCI with manufacturing data and other corporate records, which the Company subsequently provided to OCI. The Company cooperated fully with the OCI investigation. The OCI declined to identify the specific focus of its investigation involving the Company, and the Company has had no direct contact with OCI regarding the investigation since January 2001 when certain documents were requested. It is not possible to predict the outcome of this investigation at this time or its potential impact on the Company. The Company believes that it is in compliance with all applicable laws, rules and regulations.

The Securities and Exchange Commission ("SEC") informed the Company that it was investigating, under a formal order of investigation, the events relating to the March 23, 2000 *USA Today* article entitled "Breast Implant Manufacturer Under Investigation by the FDA," which was authored by Rita Rubin, and the March 23, 2000 press release issued by Mentor responding to that article, and possibly other matters. The Company cooperated fully with the SEC's investigation. In May 2002, the Company received notification from the SEC's Division of Enforcement that "This investigation has been terminated and no enforcement action has been recommended to the Commission."

Claims related to product liability are a regular and ongoing aspect of the medical device industry. At any one time, the Company is subject to claims asserted against it and is involved in product liability litigation. These actions can be brought by an individual, and/or by a group of patients purported to be a class action. The Company has carried product liability insurance on all its products, including breast implants, subsequent to May 1991 and prior to September 1985. This insurance is subject to certain self-insured retentions and limits on the policies. From September 1985 through April 1991, the Company was self insured for the majority of its surgical implant products, but had product liability insurance on the rest of its products. From June 1992 on, the Company's insurance has excluded silicone gel-filled breast implants.



In February 1999, Mentor was the plaintiff in a jury trial defending a patent exclusively licensed to Mentor by Sonique Surgical Systems, Inc., and used in ultrasonic tissue removal. Although the jury found willful infringement, the court nonetheless entered a judgment in favor of the defendants (Medical Device Alliance, Inc., Lysonics, Inc. and Misonix, Inc.). Mentor challenged the court order and in May 2001 a Federal circuit court reversed the lower court's ruling and reinstated the jury award of damages. In April 2002, the Company received \$5.4 million in full settlement of the jury award.

In addition, in the ordinary course of its business the Company experiences various types of claims that sometimes result in litigation or other legal proceedings. The Company does not anticipate that any of these proceedings will have any material adverse effect on the Company.

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

None.

PART II

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED SHAREHOLDER MATTERS.**

The Common Stock of the Company is traded on the Nasdaq National Market under the symbol MNTR. There are approximately 17 market makers for the Company's stock. The following table sets forth for the period indicated the high and low sale prices for the Common Stock reported on the Nasdaq National Market.

<u>Year Ended March 31, 2001</u>	<u>High</u>	<u>Low</u>
Quarter ended June 30, 2000	\$28.25	\$14.31
Quarter ended September 30, 2000	28.00	15.75
Quarter ended December 31, 2000	20.38	15.69
Quarter ended March 31, 2001	23.88	18.25
<u>Year Ended March 31, 2002</u>	<u>High</u>	<u>Low</u>
Quarter ended June 30, 2001	\$28.34	\$22.13
Quarter ended September 30, 2001	31.44	23.94
Quarter ended December 31, 2001	30.20	23.05
Quarter ended March 31, 2002	36.08	28.08

According to the records of the Company's transfer agent, there were approximately 1,031 holders of record of the Company's Common Stock on June 26, 2002. However, the majority of shares are held by brokers and other institutions on behalf of shareholders in approximately 5,000 accounts. The actual number of total shareholders may

be less due to shareholders holding accounts at more than one institution.

For the first three quarters of fiscal 2001, the Company declared and paid a quarterly dividend of \$.025 per share of Common Stock. In the fourth quarter of fiscal 2001, the Board of Directors approved a 20% increase in the quarterly dividend from \$.025 to \$.03 per share. In fiscal 2002, the Company declared and paid a quarterly dividend of \$.03 per share of common stock for all four fiscal quarters. It is the Company's intent to continue to pay dividends for the foreseeable future subject to among other things, Board approval, cash availability and alternative cash needs. The \$25M Credit Agreement limits the aggregate amount of dividends payable in any year to one-half of the net income of the preceding year.

#### ITEM 6. SELECTED FINANCIAL DATA.

The following table summarizes certain selected financial data of the Company and should be read in conjunction with the related Consolidated Financial Statements of the Company and accompanying Notes to Consolidated Financial Statements.

(in thousands, except per share data)	Year Ended March 31,				
	2002 <sup>(1)</sup>	2001 <sup>(1)</sup>	2000	1999	1998
Statement of Income Data:					
Net sales	\$ 321,062	\$ 268,894	\$ 249,345	\$204,576	\$181,613
Gross profit	190,607	164,198	154,687	126,609	121,145
Operating income	57,516	41,787	39,431	30,141	36,786
Income before income taxes -					
Continuing operations	59,216	46,549	42,389	30,888	38,404
Income taxes - continuing operations	17,396	14,731	13,563	10,447	13,575
Income from continuing operations	41,820	31,818	28,826	20,441	24,829
Discontinued operations, net of income tax	-	260	7,713	(6,479)	(932)
Net income	\$ 41,820	\$ 32,078	\$ 36,539	\$ 13,962	\$ 23,897
Basic earnings (loss) per share:					
Continuing operations	\$ 1.77	\$ 1.35	\$ 1.18	\$ 0.83	\$ 1.00
Discontinued operations	0.00	0.01	0.32	(0.26)	(0.04)
Basic earnings per share	\$ 1.77	\$ 1.36	\$ 1.50	\$ 0.57	\$ 0.96
Diluted earnings (loss) per share:					
Continuing operations	\$ 1.71	\$ 1.32	\$ 1.16	\$ 0.80	\$ 0.94
Discontinued operations	0.00	0.01	0.30	(0.25)	(0.03)
Diluted earnings per share	\$ 1.71	\$ 1.33	\$ 1.46	\$ 0.55	\$ 0.91
Dividends per common share	\$ 0.12	\$ 0.105	\$ 0.10	\$ 0.10	\$ 0.10
Average outstanding shares:					
Basic	23,639	23,627	24,384	24,550	24,894
Diluted	24,463	24,186	25,084	25,394	26,330
Balance Sheet Data:					
Working capital	\$ 126,556	\$ 112,461	\$ 124,141	\$106,532	\$115,656

Total assets	324,636	290,837	230,706	196,011	199,911
Long-term accrued liabilities, less current portion	12,873	10,691	-	-	-
Shareholders' equity	\$ 224,178	\$ 196,306	\$ 183,642	\$ 158,618	\$ 164,685

(1)

Results after fiscal 2000 include the impact of the Porges S.A. acquisition in February 2001.

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

In May 1999, the Company announced that its Board of Directors had decided to divest the ophthalmology business, which accounted for approximately 16% of sales in fiscal 1999. The Company substantially completed the sale of the assets of the Ophthalmology division in three separate transactions throughout fiscal year 2000. Accordingly, results of operations of the ophthalmic business are reported, on a net basis, as a single line on the financials as discontinued operations.

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

(in thousands)	Year Ended March 31,		
	2002	2001	2000
Net sales	100.0%	100.0%	100.0%
Costs and expenses			
Cost of sales	40.6	38.9	38.0
Selling, general, and administrative	34.7	37.3	39.5
Research and development	6.8	7.3	6.7
Restructuring charge	-	0.9	-
Operating income from continuing operations	17.9	15.6	15.8
Interest expense	(0.3)	(0.1)	-
Interest income	0.7	1.6	1.2
Other income, net	0.1	0.3	-
Income from continuing operations before income taxes	18.4	17.4	17.0
Income taxes	5.4	5.5	5.4
Income from continuing operations	13.0	11.9	11.6
Income from discontinued operations, net of income taxes	-	0.1	3.1
Net income	13.0%	12.0%	14.7%

**APPLICATION OF CRITICAL ACCOUNTING POLICIES**

Management's Discussion and Analysis of Financial Condition and Results of Operations addresses Mentor Corporation's consolidated financial statements, which have been prepared in accordance with accounting principles

generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its estimates and judgments. Management bases its estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management believes the following critical accounting policies, among others, affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

#### Revenue Recognition

The Company recognizes product revenue, net of discounts, returns, and rebates in accordance with Statement of Financial Accounting Standards ("SFAS") 48, "Revenue Recognition When the Right of Return Exists", and Staff Accounting Bulletin (SAB) No.101. As required by these standards, revenue is recorded when persuasive evidence of a sales arrangement exists, delivery has occurred, the buyer's price is fixed or determinable, contractual obligations have been satisfied, and collectibility is reasonably assured. These requirements are met, and sales and related cost of sales are recognized primarily upon the shipment of products, or in the case of consignment inventories, upon the notification of usage by the customer. The Company records estimated reductions to revenue for customer programs and other volume-based incentives. Should the actual level of customer participation in these programs differ from those estimated by the Company, additional adjustments to revenue are recorded. The Company also allows credit for products returned within its policy terms. The Company records at the time of sale an allowance for estimated returns, based on historical experience, recent gross sales levels and any notification of pending returns. Should the actual returns differ from those estimated by the Company, additional adjustments to revenue and cost of sales may be required.

#### Accounts Receivable

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

#### Inventories

The Company values its inventory at the lower of cost, based on the first-in first-out ("FIFO") cost method, or the current estimated market value of the inventory. The Company writes down its inventory for estimated obsolescence or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual future demand or market conditions differ from those projected by management, additional inventory valuation adjustments may be required. These adjustments would be included in cost of goods sold.

#### Warranties and Related Reserves

The Company provides an accrual for the estimated cost of product warranties and product liability claims at the time revenue is recognized. Such accruals are based on estimates, which are based on relevant factors such as historical experience, the warranty period, estimated costs, levels of insurance and insurance retentions, identified product quality issues, if any, and, to a limited extent, information developed by the insurance company using actuarial techniques. These accruals are analyzed periodically for adequacy. While the Company engages in extensive product quality programs and processes, including actively monitoring and evaluating the quality of its component suppliers, the warranty obligation is affected by reported rates of product problems and costs incurred in correcting product problems. Should actual reported problem rates or the resulting costs differ from the Company's estimates, adjustments to the estimated warranty liability may be required. These adjustments would be included in selling, general and administrative expenses.

#### Goodwill and Intangible Asset Impairment

The Company currently evaluates long-lived assets, including goodwill and other intangibles, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. In assessing the recoverability of goodwill and other intangibles, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the respective assets. If these estimates or their related assumptions change in the future, the Company may be required to record impairment charges for these assets. The Company will adopt SFAS No. 142, "Goodwill and Other Intangible Assets," effective April 1, 2002 and will be required to analyze its goodwill for impairment issues during the first quarter of fiscal 2003, and then on a periodic basis thereafter. These impairment charges would be included in the results of operations.

### RESULTS OF OPERATIONS

#### Sales

Sales for fiscal 2002 increased to \$321 million from \$269 million in 2001, an increase of 19%. Included in fiscal 2002 sales are twelve months of surgical urology and clinical and consumer healthcare product sales relating to the February 2001 acquisition of Porges S.A., compared to two months of sales included in the fiscal 2001. Porges product sales accounted for fifteen percentage points of the year-to-year growth. Sales also were negatively affected by the continued strength of the U.S. Dollar versus other currencies and the general economic slowdown in the economy. Foreign exchange rate movements had an unfavorable year-to-year impact on international sales of \$1.4 million, or less than 1% of consolidated sales.

Sales of surgical urology products increased 52% to \$94 million from \$62 million in the prior year. This growth primarily resulted from the February 2001 acquisition of Porges S.A., whose product sales are included in fiscal 2002 sales for the whole year. Porges product sales accounted for forty-eight percentage points of the year-to-year growth. Penile implant sales included incremental sales of the of the Alpha 1 Inflatable device with the new Lockout® valve introduced late in fiscal 2000. Brachytherapy sales increased slightly over the prior year as unit sales increases were partially offset as competitive pressures decreased average selling prices.

Sales of aesthetic and general surgery products increased 4% to \$163 million from \$157 million in the prior year. The Company believes that the modest growth in aesthetic product sales was primarily the result of the general economic slowdown in fiscal 2002, and the events of September 11, 2001. The sales of aesthetic product used in cosmetic surgeries were substantially even with prior year sales, as these product sales are affected more than the Company's other aesthetic products and segments by general economic conditions, as a higher proportion of these cosmetic surgeries are paid directly by the patient. However, the sales of aesthetic products used in reconstructive surgeries increased 21% over prior year sales, as a high proportion of these product sales are reimbursed by third party payers.

Sales of clinical and consumer healthcare products increased 29% to \$64 million from \$50 million in the prior year. This growth primarily resulted from the February 2001 acquisition of Porges S.A., whose product sales are included

for all of fiscal 2002. Porges product sales accounted for twenty-four percentage points of the year-to-year growth. In addition, sales of intermittent self-catheters grew 12% with the introduction of the Self-Cath Plus™ lubricious catheter in fiscal 2002, while there was a slight decline in male external catheter sales of 7%.

Sales for fiscal 2001 increased to \$269 million from \$249 million in 2000, an increase of 8%. Sales were negatively affected by the continued strength of the U.S. Dollar versus other currencies and the general economic slowdown in the economy. Included in fiscal 2001 are approximately two months of surgical urology and clinical and consumer healthcare product sales from the February 2001 acquisition of Porges S.A. Porges product sales accounted for three percentage points of the year-to-year growth. Foreign exchange rate movements had an unfavorable year-to-year impact on international sales of \$2.4 million, or approximately 1% of consolidated sales.

Sales of surgical urology products increased 18% to \$62 million from \$53 million in the prior year. This growth resulted from increased sales of the Suspend® Sling for treating female urinary incontinence, and the February 2001 acquisition of Porges S.A. Sales of Suspend® benefited from increased acceptance of this pelvic floor reconstruction in the treatment of prolapse.

Sales of aesthetic and general surgery products increased 5% to \$157 million from \$150 million in the prior year. Sales of products for reconstruction increased 6% while products used in cosmetic augmentation increased 1%. Sales of body contouring (liposuction) products declined by 14% compared to the previous year. The aesthetic product segment is affected more than the Company's other segments by general economic conditions, as a higher proportion of these surgeries are paid directly by the patient.

Sales of clinical and consumer healthcare products increased 7% from the prior year. Strong growth in the sales of intermittent catheters of 12% was partially offset by a slight decline in male external catheter sales. The results include two months of sales from the February 2001 acquisition of Porges S.A.

The Company's export sales to independent distributors accounted for 4%, 5% and 6% of net sales for fiscal years ended March 31, 2002, 2001 and 2000, respectively. In addition, 28%, 16%, and 13%, respectively, of sales in each year were from the Company's direct international sales offices.

Over the three fiscal years ended March 31, 2002, sales increases, including the effects of acquisitions, have been primarily the result of increased unit sales. General selling price changes have not been significant in recent years.

#### Cost of Sales

Cost of sales was 40.6% of net sales for fiscal 2002, compared to 38.9% in fiscal 2001. Fiscal 2002 included Porges product sales for the entire year as opposed to two months in fiscal year 2001. Porges products have an average cost of sales of approximately 60% as compared to a historic average of 38% for the rest of the Company's products and, consequently, the additional Porges product sales have diluted the gross margin product mix. This dilution was partially offset by manufacturing efficiencies in the aesthetic and clinical and consumer healthcare products.

Cost of sales was 38.9% of net sales for fiscal 2001, compared to 38.0% in fiscal 2000. The faster growth of products distributed under alliance agreements, such as brachytherapy seeds and the Suspend® Sling, continues to shift the product mix towards products with gross margins of approximately 50%, which is lower than the margin generated by products manufactured and distributed by the Company. In addition, sales of Porges products late in the fiscal year diluted the gross margin product mix slightly.

#### Selling, General and Administrative

Selling, general and administrative expenses were 34.7% of net sales in fiscal 2002 compared to 37.3%, exclusive of the restructuring charge, in fiscal 2001. The decrease as a percentage of net sales reflects cost savings from the Company's restructuring of corporate staff during the second and third quarters of fiscal 2001 and the recent

acquisition of Porges which has a lower percentage of selling, general and administrative expenses to net sales than the rest of the Company.

Selling, general and administrative expenses, exclusive of the restructuring charge, were 37.3% of net sales in fiscal 2001 compared to 39.5% in fiscal 2000. The decrease reflects lower spending on the Company's direct-to-consumer advertising campaign partially offset by increases in product liability reserves and information technology costs. In addition, cost savings from the Company's restructuring of corporate staff contributed to the improvement.

During fiscal 2001, the Company announced a reduction in corporate staff at its headquarters in Santa Barbara as part of a restructuring move to streamline operations and improve efficiency. Employees affected by the restructuring were provided with a severance package, outplacement counseling and extended benefits to help with the transition. This program resulted in a restructuring charge included in general and administrative expenses of \$2.4 million.

### Research and Development

Research and development expenses were 6.8% of net sales in fiscal 2002, a slight decrease from 7.3% in fiscal 2001. Overall spending on research and development increased by 11% from the prior year. Fiscal 2002 development costs relate primarily to the Company's automated brachytherapy workstation, accelerated product enhancement projects for existing products and new product development. Fiscal year 2002 also includes research and development costs related to Porges products, for which research and development expenses as a percentage of net sales have historically been lower than those for the Company's other products. Although the Company has successfully completed several PMAA submissions related to mammary and penile implants in recent years, the amount of spending on research and development is not expected to decrease as the focus of the Company's research and development efforts shifts towards product enhancements and new product development. In addition, the Company is committed to a variety of clinical and laboratory studies in connection with its gel-filled and saline filled mammary implants and other products.

Research and development expenses were 7.3% of net sales in fiscal 2001, an increase from 6.7% in the prior year. The increase was attributable to spending on the Company's ongoing clinical studies related to silicone gel mammary implants. In May 2000, the Company received FDA approval for saline-filled breast implants and, in July 2000 received similar regulatory clearance on our inflatable penile implants.

### Interest and Other Income and Expense

Interest expense increased to \$859 thousand in fiscal 2002, from \$276 thousand in fiscal 2001. In January 2001, the Company acquired the assets of South Bay Medical LLC. Approximately \$7 million of the purchase price was recorded as a long-term accrued liability at net present value. In December 2001, an additional \$1.7 million of long-term accrued liability was recorded at net present value related to the acquisition of certain intangible rights from ProSurg, Inc. Imputed interest on these liabilities is charged to interest expense. This imputed interest and balances outstanding on several lines of credit established to facilitate operating cash flow needs at our foreign subsidiaries accounted for the increase in interest expense over the prior year. In fiscal 2002, \$196 thousand of interest incurred on a line of credit to finance the construction of a new foreign manufacturing facility was capitalized.

Interest expense increased to \$276 thousand in fiscal 2001, from \$34 thousand in fiscal 2000. In the first quarter of fiscal 2001, the Company borrowed and repaid \$6 million to temporarily fund its stock repurchase program. During the fourth quarter of fiscal 2001, the Company borrowed \$14 million to fund its acquisition of Porges S.A. There were no borrowings in fiscal 2000, and the Company repaid \$4 million borrowed in 1999 to temporarily fund the stock repurchase program.

Interest income decreased from \$4.2 million in 2001 to \$2.2 million in fiscal 2002. The decrease is due to lower cash and marketable security balances, lower prevailing interest rates on short term investments, and a shift in the Company's investment strategy from taxable commercial paper which has a higher pretax yield to tax free municipal

bonds and similar tax advantaged investment vehicles which currently have a higher after-tax yield.

Interest income increased to \$4.2 million in 2001 from \$3.0 million in fiscal year 2000. The increase is a result of higher cash balances from operations and \$59 million in proceeds from the sale of the assets of the ophthalmic business reported as discontinued operations which was only available for investment part of fiscal 2000. Further, the Company increased its use of fully taxable investments, which have a higher coupon rate and also benefited from higher prevailing interest rates.

Other income, net primarily includes gains or losses on sales of marketable securities, disposal of assets, and foreign currency gains or losses related to the Company's foreign operations. In fiscal 2000, the Company recorded a \$3 million permanent impairment of its equity investment in Intracel Corporation. This impairment charge was offset by realized gains on the disposition of marketable securities recorded as long-term marketable securities available for sale. During fiscal 2002, the Company recorded an additional \$3 million write-down of the Company's investment in Intracel Corporation upon its bankruptcy filing. At March 31, 2002 the investment in Intracel Corporation is carried at no value. Other income, net for fiscal 2002, also includes a one-time gain of \$700 thousand related to the settlement of a dispute with Paradigm Medical Industries, a one-time foreign exchange gain of \$720 thousand on the repayment of the 15 million euro loan to partially fund the acquisition of Porges S.A., the realized gains on the disposition of long-term marketable securities available-for-sale of \$1.3 million.

In fiscal year 2001, the Company recorded a \$1 million realized gain on the disposition of marketable securities recorded as long-term marketable securities available for sale.

#### Income Taxes

The effective rate of corporate income taxes was 29.4% for fiscal 2002 and 31.6% for fiscal 2001. The decrease in the effective tax rate from fiscal 2001 to fiscal 2002 is a result of a higher proportion of income from foreign operations with lower tax rates, increased tax-exempt interest income, tax credits related to research and development, and a refund received in the fourth quarter of fiscal year 2002 related to the amendment of prior year tax returns for the Company's foreign sales corporation.

The effective rate of corporate income taxes was approximately 31.6% for fiscal 2001, a slight decrease from the fiscal 2000 rate of 32.0%.

#### Discontinued Operations

In December 1998, the Company announced a restructuring plan as part of a strategic initiative to improve the profitability and competitiveness of the ophthalmic segment of its business by reducing manufacturing costs and concentrating on those products and markets capable of sustained, long-term profitable growth. During the implementation of this plan, the Board of Directors authorized management to divest of the assets and product lines of the ophthalmic business segment. The divestiture was substantially completed in fiscal 2000 resulting in income from discontinued operations, net of tax, of \$7.7 million. In fiscal 2001, the Company recorded \$260 thousand of income from discontinued operations, net of tax of \$140 thousand, from the resolution of certain liabilities for amounts less than recorded at the time of the sale of discontinued assets.

#### Income From Continuing Operations

Income from continuing operations for fiscal 2002 was \$42 million, compared to \$32 million for the previous year, an increase of \$10 million or 30%. Increased sales, primarily from the Porges S.A. acquisition in February 2001, lower cost of goods sold and lower operating expenses as a percentage of net sales, and a tax refund increased net income, while the write-down of the Company's investment in Intracel Corporation and lower investment income reduced net income.



Income from continuing operations for fiscal 2001 was \$32 million, compared to \$29 million for the previous year. Increased sales, lower operating expenses, and increased interest income contributed to the increase. Fiscal 2001 income from discontinued operations, net of income taxes, was \$260 thousand related to the resolution of certain liabilities for amounts less than recorded at the time of disposal.

### Inflation

The Company does not believe inflation has had a material impact on the Company's operations over the three-year period ended March 31, 2002.

## **LIQUIDITY AND CAPITAL RESOURCES**

The Company had cash, cash equivalents and short-term marketable securities of \$75 million and \$64 million at March 31, 2002 and 2001, respectively. During the three years ended March 31, 2002, liquidity needs have been satisfied principally by cash flow from operations and, to a lesser extent from borrowings under the Company's line of credit. Despite significant acquisition and stock repurchase activities, the Company maintained its strong cash and financial position throughout fiscal 2002.

At March 31, 2002, working capital was \$127 million compared to \$112 million the previous year. The Company generated \$58 million of cash from continuing operations during fiscal 2002, compared to \$42 million the previous year. Increased income from continuing operations, and increases in accounts payable and accrued liabilities contributed to the increased cash flow. These amounts were partially offset by an increase in accounts receivable and inventory.

During fiscal 2002, the Company invested \$15 million in manufacturing equipment, information technology systems, and in a new manufacturing facility in Leiden, the Netherlands. The Company anticipates investing approximately \$15 million in fiscal 2003 to complete the new facility in Leiden, invest in an existing facility, purchase production equipment and upgrade and replace information technology systems.

The Company receives cash from the exercise of employee stock options. Employee stock option exercises provided \$6.9 and \$2.5 million of cash in fiscal 2002 and fiscal 2001, respectively. Proceeds from the exercise of employee stock options will vary from period to period based upon, among other factors, fluctuations in the market value of the Company's common stock relative to the exercise price of such options.

The Company's Board of Directors has authorized an ongoing stock repurchase program. The objectives of the program, among other items, are to offset the dilutive effect of the Company's employee stock option program, provide liquidity to the market and to reduce the overall number of shares outstanding. Repurchases are subject to market conditions and cash availability. During fiscal 2002, the Company repurchased 732 thousand shares for consideration of \$18.7 million. The Company intends to continue the share repurchase program in fiscal 2003 and 1.6 million shares remain authorized for repurchase.

Certain technologies related to the manufacture of mammary prostheses were developed under a 1983 agreement with a limited partnership whereby the limited partners contributed funds towards the development of the technology in exchange for payments based upon a percentage of future sales of the products utilizing the technology. The Company paid approximately \$2 million in such payments in fiscal 2000 to the partnership. The Company was the general partner for this partnership. The agreement included an option to purchase the technology and thereby terminate the partnership. In fiscal 2001, the Company exercised its option to make a lump sum payment to the limited partners in lieu of all future payments and rights according to the Agreement of Purchase and Sale between Mentor Corporation and the partnership, as amended. The limited partners could elect to be paid in cash, the Company's common stock, or a combination. This transaction was completed in the second quarter ended September 30, 2000. The limited partners elected to be paid \$1.0 million in cash and 434 thousand shares of the Company's common stock. The stock, transfer

of which is restricted by Rule 144, was valued at its fair market value on the date of issuance, of approximately \$9 million. The decrease in payments to the partners will be offset by the increased amortization of the new intangible asset and the additional common shares outstanding, thus having a neutral effect on earnings per share.

In January 2001, the Company completed the acquisition of South Bay Medical, a development stage company focused on the development of a new technology for a computer-based workstation and automated cartridge-based needle loading system for use in Brachytherapy procedures. The total consideration included \$2 million in cash, 235,293 restricted shares of the Company's Common Stock having a fair market value of \$4 million, and \$13.6 million to be paid in cash or the Company's Common Stock over the next several years. These future payments have been recorded as an acquisition obligation liability at net present value (\$11.2 million at March 31, 2002), and will continue to increase as imputed interest is recorded. Approximately \$5.9 million of the acquisition obligation liability is to be paid in shares of the Company's Common Stock valued at fair market value on the date of issuance.

In February 2001, the Company acquired Porges S.A., subsidiary of Sanofi-Synthelabo headquartered in Paris, and with manufacturing facilities in Sarlat, France. Porges holds a leading market share for urological products in France and has strong market position throughout Europe. The cash consideration paid for Porges S.A. was \$32 million.

In December 2001, Company entered into several agreements with ProSurg, Inc. to purchase certain patent rights and a supply of a bio-absorbable co-polymer product to be used the surgical treatment of incontinence. The total consideration included \$2.0 million in cash and \$2.7 million in short and long-term payments due over the next several years. The future payments have been recorded as an acquisition obligation liability at net present value and will increase with imputed interest to \$3.0 million due over the next several years.

The Company has a secured line of credit, the "\$25M Credit Agreement", for borrowings up to \$25 million, which accrue interest at the prevailing prime rate or at a mark-up over LIBOR at the Company's discretion. The \$25M Credit Agreement includes certain covenants that, among other things, limit the dividends the Company may pay and requires maintenance of certain levels of tangible net worth and debt service ratios. During fiscal 2002, the Company used the \$25M Credit Agreement to guarantee the secured loan of a vendor, in the amount of \$5.3 million, to facilitate the ramp up of production capacity related to a new product. Accordingly, although there were no borrowings outstanding under the \$25M Credit Agreement at March 31, 2002, only \$19.7 million was available for additional borrowings.

In addition, in February 2001, several lines of credit were established with local foreign lenders to facilitate operating cash flow needs at our foreign subsidiaries. These lines are at market rates of interest, unsecured, guaranteed by Mentor Corporation, and total \$5.0 million, of which \$4.4 million was outstanding, and \$.6 million was available at March 31, 2002.

In fiscal 2002, a line of credit of \$5.6 million was established to finance the construction of a new facility in Leiden, the Netherlands. The borrowings accrue interest at EURIBOR plus 0.75% and are secured by the new facility and other assets in the Netherlands. \$4.8 million was outstanding and \$.8 million was available under this line at March 31, 2002. The line of credit provides for conversion to a term loan at prevailing interest rates when construction of the new facility is completed.

At March 31, 2002, the total of short-term borrowings under all lines of credit was \$9.5 million and the weighted-average interest rate was 4.10%. The total amount of additional borrowings available to the Company under all lines of credit was \$21.1 million and \$12.1 million at March 31, 2002 and 2001, respectively. At March 31, 2001, \$16.6 million was outstanding under these lines of credit at a weighted average borrowing rate of 5.96%.

Since 1995, the Company has paid a quarterly cash dividend of \$.025 per share. On February 13, 2001, the Board of Directors approved an increase in the quarterly cash dividend to \$.03 per share, an increase of 20%. At the current rate of \$.12 per year, the aggregate annual dividend would equal approximately \$2.8 million. It is the Company's intent to

continue to pay dividends for the foreseeable future subject to among other things, Board approval, cash availability and alternative cash needs. The \$25M Credit Agreement limits the aggregate amount of dividends payable in any year to one-half of the net income of the preceding year.

On May 6, 2002, the Company announced that it had completed the acquisition of the urology business of Portex Ltd., a subsidiary of Smiths Group plc. The acquired business manufactures and markets incontinence and ostomy products primarily for the home healthcare market. The cash consideration paid for Portex Ltd. was \$10.5 million from available cash balances.

The following table summarizes contractual cash and other commercial commitments at March 31, 2002:

(in thousands)		Less Than	1-3	4-5	After 5
	Total	1 Year	Years	Years	Years
Contractual Cash Obligations					
Operating leases	\$40,668	\$3,971	\$12,138	\$7,691	\$16,868
Total Contractual Cash Obligations	\$40,668	\$3,971	\$12,138	\$7,691	\$16,868

#### Commercial Commitments

Lines of credit	\$ 9,470	\$ 9,470	\$ -	\$ -	\$ -
Guarantees	5,300	5,300	-	-	-
Other commercial commitments	18,355	4,675	11,151	700	1,829
Total Commercial Commitments	\$ 33,125	\$ 19,445	\$11,151	\$ 700	\$ 1,829

In addition the Company, in the ordinary course of business, has at any one time, purchase orders for raw materials and other supplies, which may in aggregate be significant but for which usage does not exceed one year.

The Company's principal source of liquidity at March 31, 2002 consisted of \$75 million in cash, cash equivalents and short-term marketable securities, plus \$21 million available under the existing lines of credit. The Company believes that funds generated from operations, its cash, cash equivalents and marketable securities and funds available under its line of credit agreements will be adequate to meet its working capital needs and capital expenditure investment requirements and commitments for at least the next 12 months. However, it is possible that the Company may need to raise additional funds to finance its activities beyond the next 12 months or to consummate acquisitions of other business, products or technologies. Additional funds could be raised by selling equity or debt securities to the public or to selected investors, or by borrowing money from financial institutions. In addition, even though the Company may not need additional funds, it may still elect to sell additional equity or debt securities or obtain credit facilities for other reasons. The Company may not be able to obtain additional funds on terms that would be favorable to our shareholders and the Company, or at all. If additional funds are raised by issuing additional equity securities or convertible debt securities, the ownership percentage of existing shareholders would be reduced. In addition, the equity or debt securities issued by the Company may have rights, preferences or privileges senior to those of the Company's common stock.

#### FACTORS THAT MAY AFFECT FUTURE RESULTS OF OPERATIONS

Except for the historical information contained herein, the matters discussed in this Management's Discussion are forward-looking statements, the accuracy of which is necessarily subject to risks and uncertainties. Actual results may differ significantly from the discussion of such matters in the forward-looking statements.

Due to the nature of the Company's products and business, the Company has been and will be involved in various legal actions arising in the course of business, some of which involve product liability and intellectual property claims. With respect to product liability issues, the litigation and regulatory risks will continue to exist even with respect to those products that have received or in the future may receive regulatory approval for commercial sale. It is possible that adverse results arising from product liability or intellectual property actions, as well as adverse results arising from regulatory or administrative proceedings, could negatively affect the Company's future results of operations.

The Company has been and may be in the future the subject of negative publicity, which can arise from various sources, ranging from the news media to legislative and regulatory investigations. There can be no assurance that such negative publicity will not result in a material adverse effect on the Company's future financial position, its results of operations or the market price of its stock. In addition, significant negative publicity could result in an increase in product liability claims.

The Company's products, development activities and manufacturing processes are subject to extensive and rigorous regulation by the FDA. The FDA regulates the introduction, manufacturing, labeling and record-keeping procedures for medical devices. The process of obtaining marketing clearance and approval from the FDA for new products and existing products can be time-consuming and expensive, and there is no assurance that such clearances or approvals will be granted or that FDA review will not involve delays that would adversely affect the Company's ability to commercialize additional products or additional applications for existing products. In addition, certain of the Company's products that are in the research and development stage may be subject to a lengthy and expensive pre-market approval process with the FDA. Product approvals by the FDA can also be withdrawn due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial approval. The FDA could also limit or prevent the manufacture or distribution of the Company's products and has the power to require the recall of such products. The FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretations made by the FDA or other regulatory bodies will not adversely affect the Company. The FDA, various state agencies and foreign regulatory agencies inspect the Company and its facilities from time to time to determine whether the Company is in compliance with various regulations including manufacturing practices, validation, testing, quality control, product labeling, and reporting. The FDA also reviews promotional materials for compliance with requirements. A determination that the Company is in violation of such regulations could lead to imposition of penalties, product recalls, consent decrees, product seizures, civil penalties, or prosecution.

As a manufacturer of medical devices, the Company's manufacturing processes and facilities are subject to regulation and review by international regulatory agencies for products sold internationally. The Company has obtained a CE mark (CE marking indicates conformity to the Medical Device Directives) for its products sold in Europe by demonstrating compliance with the ISO 9001, EN46001 and ISO13485 international quality system standards. Medical device laws and regulations are also in effect in some of the other countries to which the Company exports its products. These range from comprehensive device approval requirements for some or all of the Company's medical device products to requests for product data or certifications. Failure to comply with these international regulatory standards and requirements could affect the Company's ability to market and sell its products in these markets and have a significant negative impact on sales and results of operations.

A significant portion of the Company's products sales are sold to health care providers whose costs are reimbursed by third-party payers including the Medicare and Medicaid programs and private payers, such as group health insurance programs and managed care plans. The Company's products are sold principally to hospitals, physicians, home health care suppliers, and others that receive reimbursement for the products and services they provide from these third-party payers. As a result, demand for the Company's products is dependent in part on the coverage and reimbursement

policies of these Third-party payers. The Company's product revenue and results of operations could be affected negatively if Third-party payers discontinue or limit reimbursement for use of the Company's products, or if other treatment options are perceived to be more profitable.

Each of the Company's major business segments operates its manufacturing, warehousing and research and development activities in a single facility. While the Company has some limited protection in the form of basic insurance coverage, the Company's operating results and financial condition would be materially adversely affected in the event of a fire or similar catastrophe.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

The following discussion about the Company's market risk disclosures involves forward-looking statements. Actual results could differ materially from those projected in the forward-looking statements. The Company is exposed to market risk related to changes in interest rates and foreign exchange rates. The Company generally does not use derivative instruments.

The Company maintains a portfolio of highly liquid cash equivalents, with maturities of three months or less from the date of purchase. The Company also has current marketable securities, consisting primarily of municipal bonds and commercial paper that are of limited credit risk and have contractual maturities of less than two years. Given the short-term nature of these investments, the Company is not subject to significant interest rate risk.

A portion of the Company's operations consists of sales activities in foreign markets. The Company manufactures its products primarily in the United States and Europe and sells them outside the U.S. through a combination of international distributors and wholly owned sales offices. Sales to third-party distributors and to the wholly owned sales offices are transacted in U.S. dollars or in Euros. The sales offices invoice their customers in their local currency.

As a result, the Company's financial results could be significantly affected by factors such as changes in foreign currency exchange rates or weak economic conditions in those foreign markets. The principal exposure on sales to third-party distributors stems from the potential for weak economic conditions in the foreign market, thus weakening the foreign currency, decreasing the customer's buying power and potentially decreasing the Company's sales. The Company's exposure on sales to its subsidiaries consists of (1) the exposure related to a weakening local currency when payment of the related payables are made resulting in more local currency to pay off the U.S. denominated payable than when it was originally recorded, thus lowering the subsidiaries' earnings, and (2) the exposure that upon translation of the subsidiaries' monthly financial statements, a weakening local currency would cause sales made in local currency to be recorded in a lower amount of U.S. dollars than if the currency had been stable as compared to the U.S. dollar. However, in the latter instance, operating expenses would also be translated at lower amounts and, accordingly, the effect on net income would be mitigated. The Company does not currently hedge any of these exposures.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The response to this item is submitted pursuant to Item 14 of this Annual Report on Form 10-K and incorporated herein by reference.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.**

The information required by this item, other than the information regarding Executive Officers set forth in Item 1, Business, is herein incorporated by reference to portions of the Proxy Statement for the Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended March 31, 2002.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this item is herein incorporated by reference to portions of the Proxy Statement for Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended March 31, 2002.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT.**

The information required by this item is herein incorporated by reference to portions of the Proxy Statement for Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended March 31, 2002.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.**

The information required by this item is herein incorporated by reference to portions of the Proxy Statement for Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended March 31, 2002.

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PART IV

**ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.**

(a)(1)

Consolidated Financial Statements

Report of Ernst & Young LLP, Independent Auditors

Consolidated Balance Sheets as of March 31, 2002 and 2001

Consolidated Statements of Income for the Years Ended March 31, 2002, 2001 and 2000

Consolidated Statements of Changes in Shareholders' Equity for the Years Ended March 31, 2002, 2001 and 2000

Consolidated Statements of Cash Flows for the Years Ended March 31, 2002, 2001 and 2000

Notes to Consolidated Financial Statements

(a)(2)

Consolidated Financial Statement Schedules

Schedule II - Valuation and Qualifying Accounts and Reserves

All other schedules are omitted because they are not required, inapplicable, or the information is otherwise shown in the consolidated financial statements or notes thereto.

(a)(3)

Exhibits

The information required by this item is incorporated by reference to the Exhibit Index in this report on page 58.

(b)

Reports on Form 8-K

None

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Report of ERNST & YOUNG LLP, Independent Auditors

Board of Directors and Shareholders

Mentor Corporation

We have audited the accompanying consolidated balance sheets of Mentor Corporation as of March 31, 2002 and 2001, and the related consolidated statements of income, changes in shareholders' equity and cash flows for each of the three years in the period ended March 31, 2002. Our audits also included the financial statement schedule listed in the Index at Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Mentor Corporation at March 31, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended March 31, 2002, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ERNST & YOUNG LLP

Los Angeles, California

May 13, 2002

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MENTOR CORPORATION  
CONSOLIDATED BALANCE SHEETS

(in thousands)	March 31,	
	2002	2001
<u>Assets</u>		
Current assets:		
Cash and cash equivalents	\$ 60,398	\$ 63,854
Marketable securities	14,106	584
Accounts receivable, net of allowance for doubtful accounts of \$3,870 in 2002 and \$3,578 in 2001	64,786	57,427
Inventories	47,404	46,721
Deferred income taxes	11,950	10,116
Prepaid expenses and other	12,488	9,331
Total current assets	211,132	188,033
Property and equipment, net	54,656	51,149
Intangible assets, net	37,588	37,773
Goodwill, net	9,155	6,547
Long-term marketable securities and investments	11,752	5,704
Other assets	353	1,631
	\$ 324,636	\$ 290,837
<u>Liabilities and shareholders' equity</u>		
Current liabilities:		
Account payable and accrued liabilities	\$ 70,423	\$ 55,246
Income taxes payable	3,979	2,992
Dividends payable	704	710
Short-term bank borrowings	9,470	16,624
Total current liabilities	84,576	75,572
Deferred income taxes	3,009	8,268
Long-term accrued liabilities	12,873	10,691
Commitments and contingencies		
Shareholders' equity:		
Common Stock, \$.10 par value:		
Authorized - 50,000,000 shares; issued and outstanding--		
23,472,952 shares in 2002;		
23,671,770 shares in 2001;	2,347	2,367



Capital in excess of par value	-	7,625
Accumulated other comprehensive income (loss)	(6,487)	(4,282)
Retained earnings	228,318	190,596
	224,178	196,306
	\$ 324,636	\$ 290,837

See notes to consolidated financial statements.

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MENTOR CORPORATION  
CONSOLIDATED STATEMENTS OF INCOME

(in thousands, except per share data)	Year Ended March 31,		
	2002	2001	2000
Net sales	\$ 321,062	\$ 268,894	\$ 249,345
Costs and expenses:			
Cost of sales	130,455	104,696	94,658
Selling, general, and administrative	111,285	100,379	98,555
Research and development	21,806	19,632	16,701
Restructuring charge	-	2,400	-
	263,546	227,107	209,914
Operating income	57,516	41,787	39,431
Interest expense	(859)	(276)	(34)
Interest income	2,217	4,209	2,982
Other income, net	342	829	10
Income from continuing operations before income taxes	59,216	46,549	42,389
Income taxes	17,396	14,731	13,563
Income from continuing operations	41,820	31,818	28,826
Income from discontinued operations, net of income taxes	-	260	7,713
Net income	\$ 41,820	\$ 32,078	\$ 36,539
Basic earnings per share:			
Continuing operations	\$ 1.77	\$ 1.35	\$ 1.18
Discontinued operations	-	0.01	0.32
Basic earnings per share	\$ 1.77	\$ 1.36	\$ 1.50
Diluted earnings per share:			
Continuing operations	\$ 1.71	\$ 1.32	\$ 1.16
Discontinued operations	-	0.01	0.30
Diluted earnings per share	\$ 1.71	\$ 1.33	\$ 1.46

See notes to consolidated financial statements.

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**MENTOR CORPORATION**  
**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY**

(in thousands)	Common Shares Outstanding	Common Stock \$.10 Par Value	Capital in Excess of Par Value	Accumulated Other Comprehensive Income (loss)	Retained Earnings	Total
Balance March 31, 1999	24,549	\$ 2,455	\$ 21,502	\$ (261)	\$ 134,922	\$ 158,618
Comprehensive income:						
Net income	-	-	-	-	36,539	36,539
Foreign currency translation adjustment	-	-	-	(1,553)	-	(1,553)
Unrealized gain on investments	-	-	-	4,137	-	4,137
Comprehensive income						39,123
Exercise of stock options	572	57	5,608	-	-	5,665
Income tax benefit arising from the exercise of stock options	-	-	2,077	-	-	2,077
Repurchase of common stock	(912)	(91)	(19,311)	-	-	(19,402)
Dividends declared (\$ .10 per share)	-	-	-	-	(2,439)	(2,439)
Balance March 31, 2000	24,209	\$ 2,421	\$ 9,876	\$ 2,323	\$ 169,022	\$ 183,642
Comprehensive income:						
Net income	-	-	-	-	32,078	32,078
Foreign currency translation adjustment	-	-	-	(2,217)	-	(2,217)
Unrealized loss on investments	-	-	-	(4,388)	-	(4,388)
Comprehensive income						25,473
Exercise of stock options	286	29	2,458	-	-	2,487
Issuance of common stock in acquisition of intangible assets	435	43	9,079	-	-	9,122
Issuance of common stock in acquisition of South						

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Bay Medical LLC	235	24	3,976	-	-	4,000
Income tax benefit arising from the exercise of stock options	-	-	2,133	-	-	2,133
Repurchase of common stock	(1,493)	(150)	(19,897)	-	(8,022)	(28,069)
Dividends declared (\$ .105 per share)	-	-	-	-	(2,482)	(2,482)
Balance March 31, 2001	23,672	\$ 2,367	\$ 7,625	\$ (4,282)	\$ 190,596	\$ 196,306

MENTOR CORPORATION  
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (continued)

(in thousands)	Common Shares Outstanding	Common Stock \$ .10 Par Value	Capital in Excess of Par Value	Accumulated Other Comprehensive Income (loss)	Retained Earnings	Total
Comprehensive income:						
Net income	-	-	-	-	41,820	41,820
Foreign currency translation adjustment	-	-	-	(2,015)	-	(2,015)
Unrealized loss on investments	-	-	-	(190)	-	(190)
Comprehensive income						39,615
Exercise of stock options	533	53	6,777	-	-	6,830
Income tax benefit arising from the exercise of stock options	-	-	2,975	-	-	2,975
Repurchase of common stock	(732)	(73)	(17,377)	-	(1,265)	(18,715)
Dividends declared (\$ .12 per share)	-	-	-	-	(2,833)	(2,833)
Balance March 31, 2002	23,473	\$ 2,347	\$ -	\$ (6,487)	\$ 228,318	\$ 224,178

See notes to consolidated financial statements.

MENTOR CORPORATION  
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended March 31,		
	2002	2001	2000

Cash From Operating Activities:

Income from continuing operations	\$41,820	\$31,818	\$28,826
Adjustments to derive cash flows from continuing operating activities:			
Depreciation	9,982	8,528	7,760
Amortization	3,866	1,812	973
Deferred income taxes	(4,799)	(1,438)	529
Tax benefit from exercise of stock options	2,975	2,133	2,077
Loss (gain) on sale of assets	456	(64)	401
Imputed interest on long-term liabilities	512	-	-
(			
	301	(1,142)	(134)
Gain) loss on long-term marketable securities and investment write-downs, net			
Changes in operating assets and liabilities:			
Accounts receivable	(8,366)	2,144	(7,879)
Inventories and other current assets	(5,338)	(3,063)	(5,645)
Accounts payable and accrued liabilities	16,025	3,173	11,631
Income taxes payable	997	(1,810)	(4,994)
Net cash provided by continuing operating activities	58,431	42,091	33,545
Net cash provided by (used for) discontinued operating activities	-	260	(8,557)
Net cash provided by operating activities	58,431	42,351	24,988

Cash From Investing Activities:

Purchases of property and equipment	(15,094)	(7,457)	(9,195)
Purchases of intangibles	(166)	(2,710)	(2,240)
Purchases of marketable securities	(161,200)	(75,552)	(50,715)
Sales of marketable securities	140,329	129,870	3,757
Acquisitions, net of cash acquired	(4,347)	(32,896)	-
Other, net	(46)	(56)	(1,028)
Net cash (used for) provided by continuing investing activities	(40,524)	11,199	(59,421)
Net cash provided by discontinued investing activities	-	-	59,392
Net cash (used for) provided by investing activities	(40,524)	11,199	(29)

Cash From Financing Activities:

Repurchase of common stock	(18,715)	(28,069)	(19,402)
Proceeds from exercise of stock options	6,830	2,487	5,665
Dividends paid	(2,839)	(2,380)	(2,442)
Borrowings under line of credit agreements	6,825	19,953	-
Repayments under line of credit agreements	(13,372)	(6,000)	(4,000)
Net cash used for financing activities	(21,271)	(14,009)	(20,179)

Effect of currency exchange rates on cash and cash equivalents	(92)	-	-
Increase (decrease) in cash and cash equivalents	(3,456)	39,541	4,780
Cash and cash equivalents at beginning of year	63,854	24,313	19,533
Cash and cash equivalents at end of year	\$60,398	\$63,854	\$24,313
Supplemental cash flow information			
Cash paid during the year for:			
Income taxes	\$ 18,945	\$14,009	\$ 8,365
Interest	\$ 645	\$ 152	\$ 51
Supplemental non-cash investing and financing activities			
Issuance of common stock in acquisition of South Bay Medical	\$ -	\$ 4,000	\$ -
Issuance of common stock in acquisition of intangible assets	\$ -	\$ 9,122	\$ -
Liabilities accrued related to the acquisition of intangible assets	\$ 2,685	\$10,720	\$ -
See notes to consolidated financial statements.			

MENTOR CORPORATION  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
MARCH 31, 2002

Note A - Summary of Significant Accounting Policies

Business Activity

Mentor Corporation was incorporated in April 1969. The Company develops, manufactures and markets a broad range of products for the medical specialties of plastic and general surgery and urology. The Company's products are sold to hospitals, physicians and through various health care dealers, wholesalers, and retail outlets. The results of operations for the discontinued ophthalmic segment of the business are presented as discontinued operations and not included in continuing operations.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and all of its subsidiaries in which a controlling interest is maintained. For those subsidiaries where the Company owns less than 100%, the outside shareholders' interests are treated as minority interests. All intercompany accounts and transactions have been eliminated. Certain prior year amounts in previously issued financial statements have been reclassified to conform to the current year presentation. Financial information presented in the Notes to Consolidated Financial Statements excludes discontinued operations, except where noted.

Cash Equivalents, Marketable Securities, and Long-Term Marketable Securities and Investments

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

The Company considers its marketable securities available-for-sale as defined in Statement of Financial Accounting Standards No. 115. Realized gains and losses and declines in value considered to be other than temporary are included in income. The cost of securities sold is based on the specific identification method. For short-term marketable securities, there were no material realized or unrealized gains or losses nor any material differences between estimated

fair values, based on quoted market prices, and the costs of securities in the investment portfolio as of March 31, 2002 and 2001. Short-term investments, except auction rate securities, mature between three months and one year from the purchase date. The Company's short-term marketable securities consist primarily of U.S., state and municipal government obligations auction rate securities, and investment grade corporate obligations including commercial paper. Auction rate securities carry interest or dividend rates that reset every 28 days but have contractual maturities of greater than one year.

The Company's long-term marketable securities and investments include investments in Federal Home Loan Bank and Mortgage Association bonds (FHLM bonds) with maturities of two to four years. During fiscal 1998, the Company made a \$6 million equity investment in Intracel Corporation as part of an agreement to develop a bladder cancer treatment. The investment was valued at cost as quoted market prices were not available. During fiscal 2000, the Company recorded a \$3 million charge to other income related to the investment. In September 2001, Intracel filed for protection under Chapter 11 of the Bankruptcy Code. After evaluation of the filing, the Company recorded an additional \$3 million write-down as a charge to other income in the quarter ending December 31, 2001. As a result of these two write-downs, the investment in Intracel is now recorded at no value. The Company recorded a one-time gain in other income for the quarter ending December 31, 2001 upon the receipt of 350,000 shares of Paradigm in settlement of a stock registration dispute. The shares were valued at \$700,000 based upon the quoted price on the date received.

During the year ended March 31, 2002, the Company sold a portion of its NASI and Paradigm securities and realized a pre-tax gain of \$1.3 million, which is reflected in other income, net.

Available-for-sale investments at March 31, 2002 were as follows:

	Adjusted	Gross Unrealized	Gross Unrealized	Estimated Fair
(in thousands)	Cost	Gains	Losses	Value
Cash balances	\$11,417	\$ -	\$ -	\$11,417
Bank time deposits	1,175	-	-	1,175
Money market mutual funds	48,981	-	-	48,981
Marketable equity securities	2,076	774	-	2,850
U.S., State and Municipal agency obligations	21,653	-	(98)	21,555
Corporate debt securities	278	-	-	278
Investment in Intracel	-	-	-	-
Total available-for-sale investments	\$85,580	\$774	\$(98)	\$86,256
Included in cash and cash equivalents	\$60,398	\$ -	\$ -	\$60,398
Included in current marketable securities	14,106	-	-	14,106
Included in long-term marketable securities and investments	11,076	774	(98)	11,752