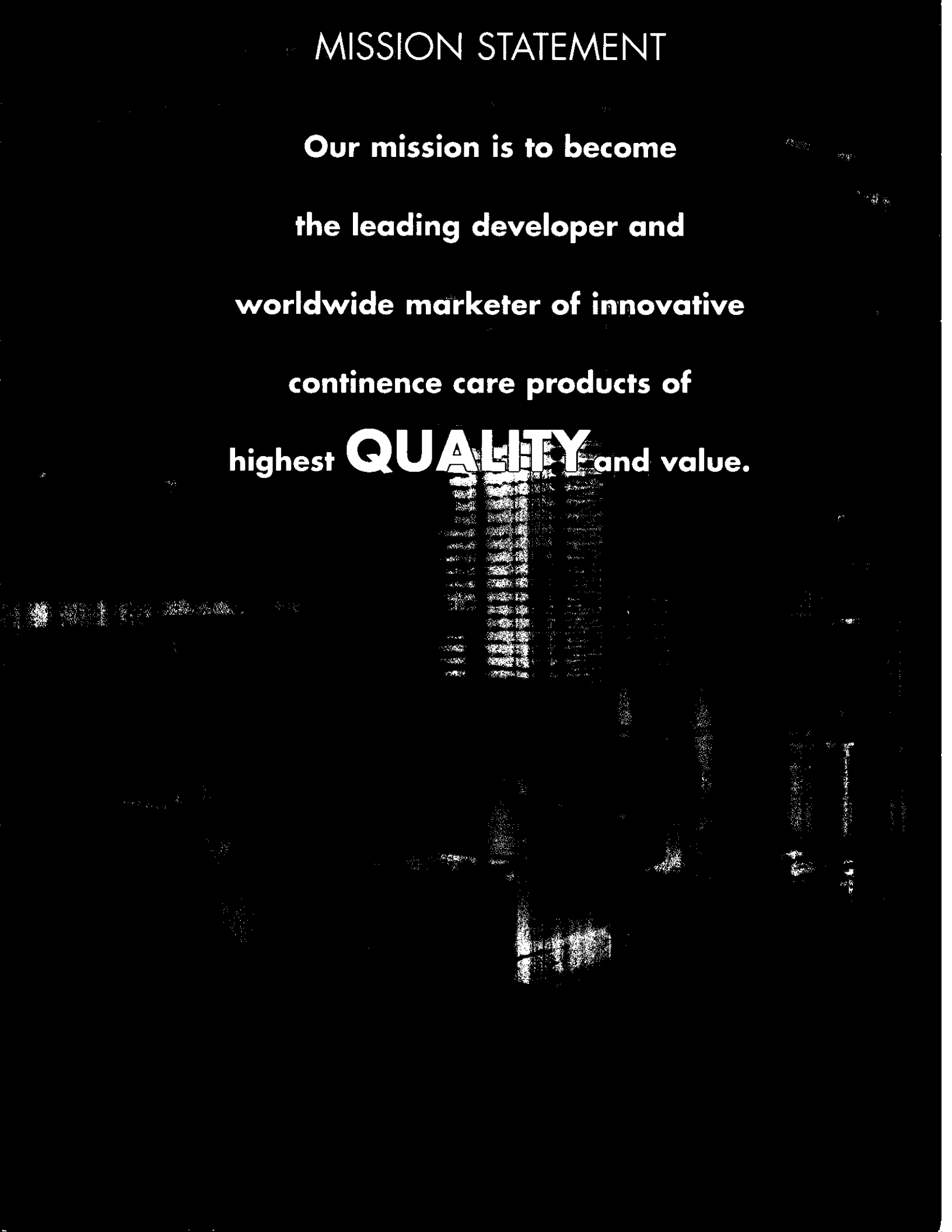
QUALITY:
ALL THE TIME

ANNUAL REPORT

Rochester® MEDICAL

MISSION STATEMENT

Our mission is to become the leading developer and worldwide marketer of innovative continence care products of highest QUALITY and value.



ANTHONY J. CONWAY
Chief Executive Officer & President

DEAR SHAREHOLDERS:

Fiscal 2007 was an excellent year for Rochester Medical. Top and bottom lines were improved significantly and we judiciously invested to support future growth. We look forward to continued progress ahead.

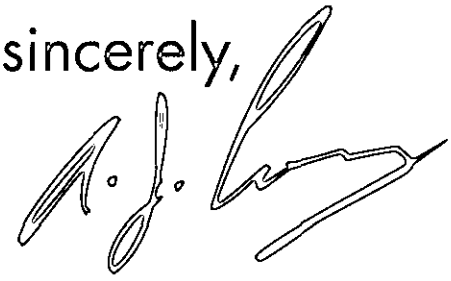
Because unsurpassed quality is central to every aspect of Rochester Medical, it is the feature of this Annual Report. We are genuinely a Quality Driven Company. Our leading edge technologies and global market presence would not be sustained without our commitment to quality.

As you page through our report you will learn how our state of the art Quality System exceeds the highest International Standards. You'll also see how our carefully controlled quality programs involve all parts of the Company from Hiring and Training through Product Development and Testing to Production, Marketing, Sales, and Customer Service.

Our entire organization is designed and monitored to ensure our customers receive the very best experience possible with Rochester Medical products and services.

We are all extremely proud of our exceptional performance in this regard and believe that our continued dedication to Quality and Integrity fosters continuing success. I thank all of you and all of our employees for contributing to another good year.

sincerely,



a **quality** system:

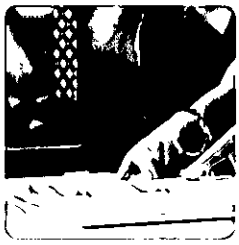
results in state-of-the-art achievements.

1991	Development of quality system in compliance with FDA requirements.
1997	Certification to *ISO9001:1994* and *EN46001:1996* quality system standards and compliance with the European Medical Device Directive.
2002	Certification to *ISO13485:1996* and compliance with the Canadian Medical Device Regulation.
2005	Certification to *ISO13485:2003.*
2007	Successful audit per *ISO13485:2003* ensuring continuing compliance.

begins and ends with the customer.

In our business, the customer is ultimately the patient. Meeting patients' needs with products and services they can continually trust, time after time, has always been the main focus of Rochester Medical Corporation. From day one, Rochester Medical has been dedicated to quality innovation, production, testing, service, distribution, and perhaps most important of all...

QUALITY THROUGH INTEGRITY.



QUALITY-DRIVEN INNOVATION:

starts with a quality management system.

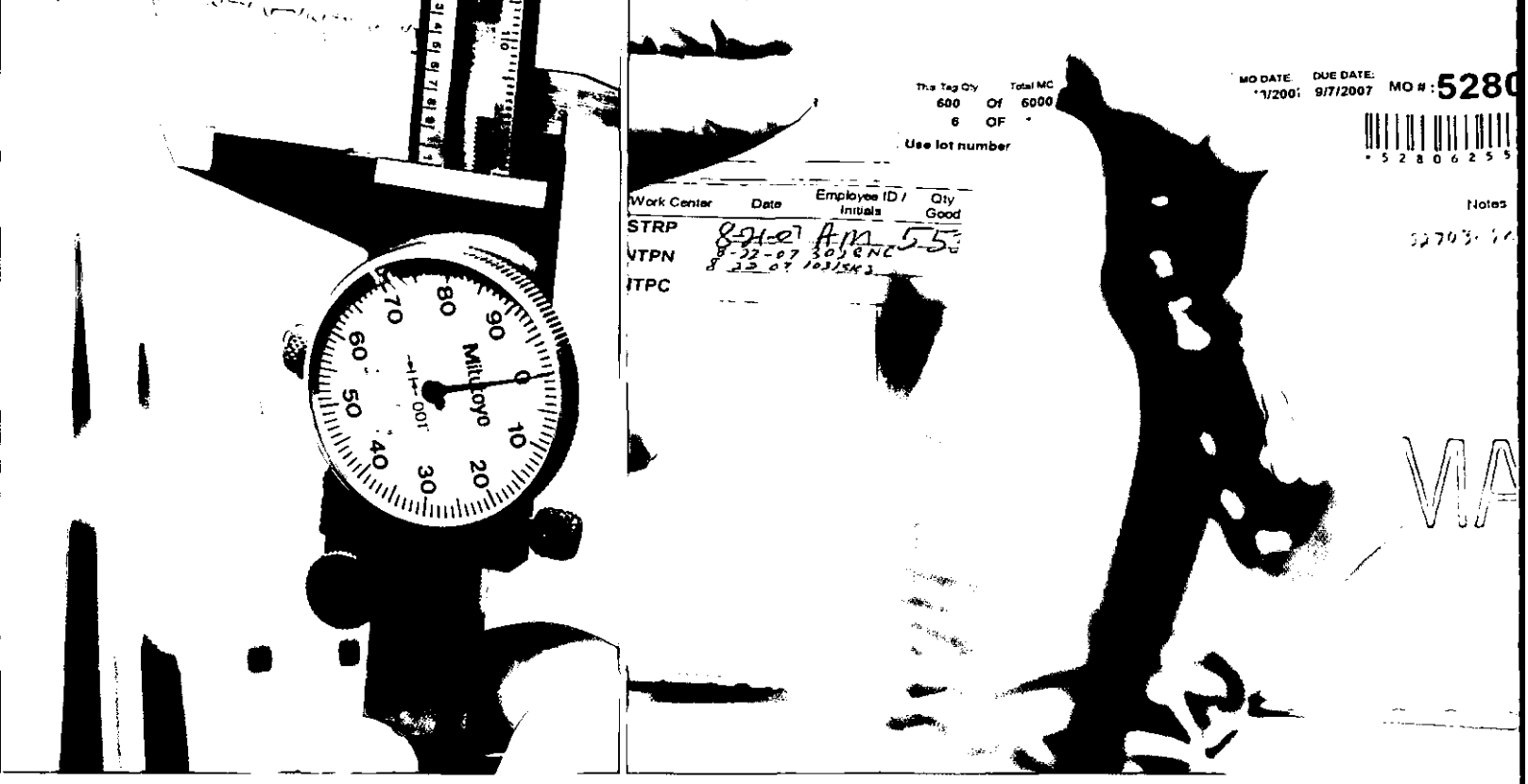
At Rochester Medical, we constantly strive to innovate and improve our products and services. To achieve this goal, the customer is always first and foremost in our minds. Our Quality System ensures that our efforts to invent and innovate are done within a formal framework with careful analysis of what is best for the patient.

QUALITY DESIGN & PRODUCTION:

products that satisfy customers' needs.

By implementing Rochester Medical's Quality System, we ensure that every device we manufacture meets and exceeds the needs of both clinicians and their patients. From the initial conceptual stages to the repeat delivery of millions of devices throughout the world, the entire process is precisely controlled, resulting in products considered to be the best in their classes. All thanks in large part to our outstanding Quality System.


COOL
(7.3mm)



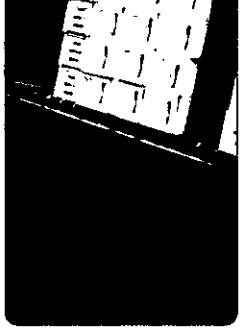
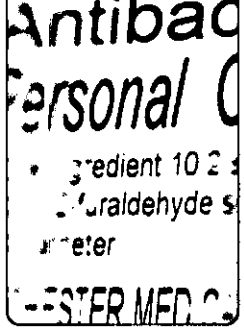
QUALITY TESTING EARNING TRUST:

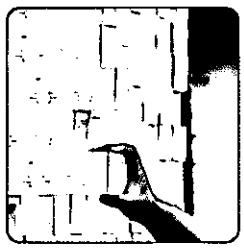
product evaluation at every step.

Every process at Rochester Medical is validated, controlled, and monitored in order to produce consistently high-quality products. Our devices are regularly subjected to rigorous inspection and test regimens assuring a quality product, time after time.

CONSISTENT, ACCURATE TESTING

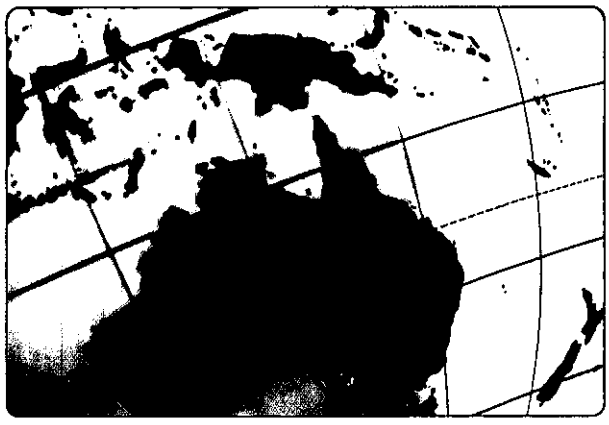
Rochester Medical continuously verifies quality and safety, ensuring a level of trust from users of our products each and every time they are used. An example of this testing: every Foley Catheter Balloon we produce is tested twice to ensure top performance.

QUALITY SERVICE & DISTRIBUTION:

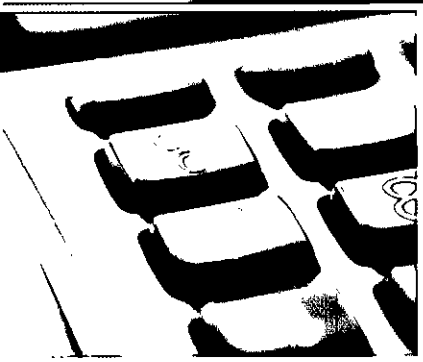
offering solutions throughout the world.

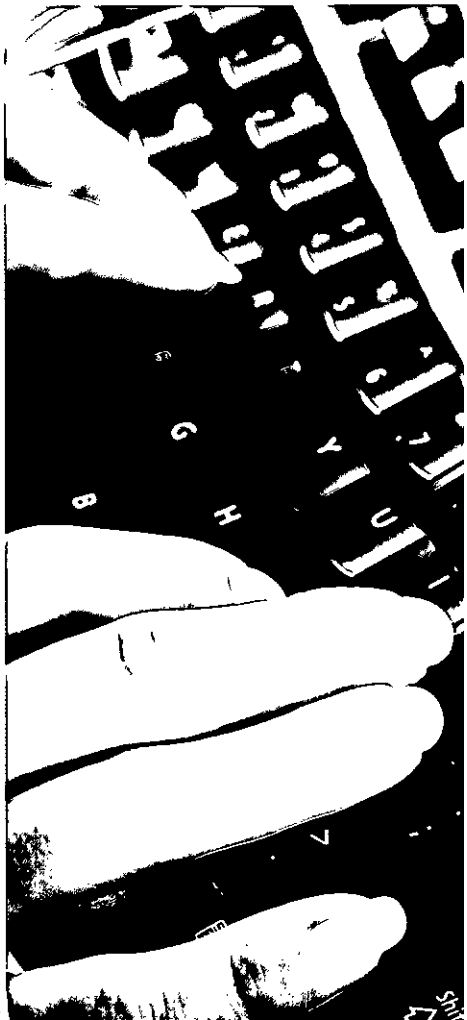


Rochester Medical understands that true customer satisfaction can only be attained through high quality experiences with our courteous staff, exceptional products, and prompt, worldwide distribution. We are continuously dedicated to providing all three.

CUSTOMER SERVICE

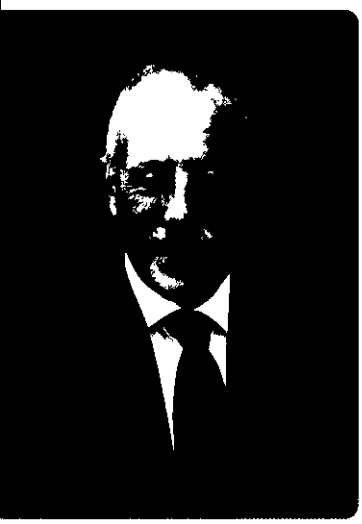
Rochester Medical's worldwide employee group is committed to exceptional customer service. Combining fast, friendly knowledge with the latest technology ensures a seamless interface with Rochester Medical clients and customers throughout the world.



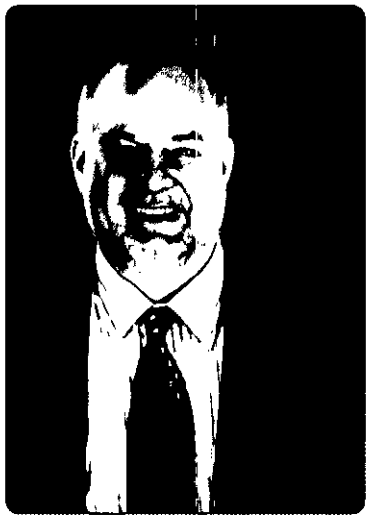


2007 Management Team

01. ANTHONY J. CONWAY – *Chief Executive Officer, President*
02. DARA LYNN HORNER – *Vice President, Marketing*
03. DAVID A. JONAS – *Chief Financial Officer, Treasurer*
04. HUGH MCLEOD – *General Manager, Rochester Medical Ltd, U.K.*
05. ERIC RICKMAN – *National Sales Director West*
06. MARISSA ANDERSON – *Human Resources Generalist*
07. LONNIE BOE – *Executive Secretary to CEO*
08. BRAD DUFFY – *National Sales Director East*
09. PHILIP J. CONWAY – *Vice President, Production Technology*
10. ROB ANGLIN – *Director of Quality & Regulatory*
11. DEBORAH PERKIN – *National Sales Manager, U.K.*
12. MARK FOOTE – *Director of International Sales*
13. MARTYN R. SHOLTIS – *Corporate Vice President*
14. JIM CARPER (not pictured) – *Marketing Director*








01. 02. 03. 04. 05. 06.

07. 08. 09. 10. 11. 12. 13. 14.

2007 Board of Directors

01. DARNELL L. BOEHM
Principal & Director of Darnell L. Boehm & Associates

02. BENSON F. SMITH
Founding Partner of The Sales Research Group, Chairman of the Board of the National Association for Continence

03. ROGER W. SCHNOBRICH
President of Waynorth, Ltd

04. ANTHONY J. CONWAY
Chairman of the Board, Chief Executive Officer, President, Founder

05. PETER R. CONWAY
Chief Executive Officer of Halcon Corporation (not pictured)

ALL THE TIME

CORPORATE INFORMATION:

Independent Public Accountants:
McGladrey & Pullen LLP
801 Nicollet Avenue
11th Floor, West Tower
Minneapolis, Minnesota 55402 USA

Legal Counsel:
Dorsey & Whitney LLP
50 South Sixth – Suite 1500
Minneapolis, Minnesota 55402-1498 USA

Stock Transfer Agent & Registrar:
Wells Fargo
P.O. Box 64854
Saint Paul, Minnesota 55164-0854 USA
US Toll-Free: 800-468-9716

Securities Information:
The Company's shares are publicly traded on the NASDAQ Stock Market under the symbol ROCM. Following are the quarterly high and low closing prices (post 11/20/06 2:1 split) of the Company's common stock as reported on the NASDAQ Stock Market (fiscal quarters).

FQ '06	1st	2nd	3rd	4th
high	$5.10	$6.37	$7.75	$8.12
low	$4.55	$5.08	$6.22	$7.05
FQ '07	**1st**	**2nd**	**3rd**	**4th**
high	$12.58	$22.78	$29.48	$19.04
low	$7.75	$12.46	$14.57	$13.70

Form 10-K Availability:
Copies of the Company's Form 10-K for the 2007 Fiscal Year, filed with the Securities and Exchange Commission, are available to any shareholder at no charge upon request from:

Investor Relations
Rochester Medical Corporation
One Rochester Medical Drive
Stewartville, Minnesota 55976 USA

DIRECTORS:

Anthony J. Conway – *Founder of the Company, Chairman of the Board, Chief Executive Officer, President, and Secretary.*

Darnell L. Boehm – *Serves on the Board of Directors for Aetrium, Inc. Previously served as a Director of ALPNET, Inc. He is also the principal of Darnell L. Boehm & Associates.*

Peter R. Conway – *Chief Executive Officer of Halcon Corporation.*

Roger W. Schnobrich – *Formerly of Counsel with the law firm of Hinshaw & Culbertson. Prior to joining Hinshaw & Culbertson, Mr. Schnobrich was a partner in the law firm of Popham, Haik, Schnobrich and Kaufman Ltd. He is the President of Waynorth, Ltd.*

Benson F. Smith – *Currently CEO of BFS & Associates, LLC, and is a Founding Partner of The Sales Research Group, LLC. Former President and Chief Operating Officer of C.R. Bard, Inc. Mr. Smith also currently serves on the Board of Directors for Teleflex, Inc., Zoll Medical, and Solace Therapeutics.*

EXECUTIVE OFFICERS:

Anthony J. Conway
Chief Executive Officer and President

David A. Jonas
Chief Financial Officer and Treasurer

Martyn R. Sholtis
Corporate Vice President

Philip J. Conway
Vice President, Production Technologies

Dara Lynn Horner
Vice President, Marketing

Corporate Headquarters:
Rochester Medical Corporation
One Rochester Medical Drive
Stewartville, Minnesota 55976 USA

Contact:
phone: 507-533-9600
fax: 507-533-9725
web: www.rocm.com

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

Form 10-K

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

For fiscal year ended September 30, 2007

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

Commission File Number: 0-18933

Rochester Medical Corporation

Minnesota	**41-1613227**
State of Incorporation	*IRS Employer Identification No.*

One Rochester Medical Drive
Stewartville, Minnesota 55976
(507) 533-9600
Address of Principal Executive Offices and Telephone Number

Securities Registered Pursuant to Section 12(b) of the Act:

Common Stock without par value	**Nasdaq Global Market**
Title of each class	*Name of each exchange on which registered*

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by checkmark if the registrant is a well-known seasoned issuer, as defined by Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by checkmark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

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

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

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

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

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

The aggregate market value of voting stock held by non-affiliates based upon the closing Nasdaq sale price on March 30, 2007 was $218,412,316.

Number of shares of common stock outstanding on November 1, 2007 was 11,690,886 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's Proxy Statement for its 2008 Annual Meeting of Shareholders are incorporated by reference in Part III.

Table of Contents

PART I

ITEM 1. Business

Overview

Rochester Medical Corporation ("we," "our," or "us") develops, manufactures and markets a broad line of innovative, technologically enhanced PVC-free and latex-free urinary continence and urine drainage care products for the extended care and acute care markets. Our extended care products include a line of male external catheters for managing male urinary incontinence and a line of intermittent catheters for managing both male and female urinary retention. Along with our full line of silicone male external catheters, we also sell a line of latex male external catheters in the United Kingdom. Our extended care products also include the *FemSoft® Insert*, a soft, liquid-filled, conformable urethral insert for managing female stress urinary incontinence in adult females. Our acute care products include a line of standard Foley catheters and our *RELEASE-NF® Catheter*, an antibacterial Foley catheter that reduces the incidence of hospital acquired urinary tract infection, or UTI. A small percentage of our extended care products also are used in the acute care market.

We market our products under our *Rochester Medical®* brand through a direct sales force in the United States and United Kingdom and through independent distributors in other international markets. We also supply our products to several large medical product companies for sale under private label brands owned by these companies.

Extended Care Products

Male External Catheters. Our male external catheters ("MECs") are self-care, disposable devices for managing male urinary incontinence. We manufacture and market six models of silicone male external catheters: the *UltraFlex®*, *Pop-On®*, *Wide Band®*, *Natural®*, *Clear Advantage®* and *Transfix®* catheters. The *UltraFlex, Clear Advantage* and *Transfix Style 1* catheters have adhesive positioned midway down the catheter sheath. The "*Pop-On*" and *Transfix Style 2* catheters have a sheath that is shorter than that of a standard male external catheter and has adhesive applied to the full length of the sheath. It is designed to accommodate patients who require shorter-length external catheters. Our *Wide Band* and *Transfix Style 3* self-adhering male external catheters have an adhesive band which extends over the full length of the sheath, providing approximately 70% more adhesive coverage than other conventional male external catheters. The full length and forward placement of the *Wide Band* adhesive is designed to reduce adhesive failure and the resulting leakage, which is a common complaint among users of male external catheters. The *Natural* catheter is a non-adhesive version of our male external catheter.

All models of our male external catheters are produced in five sizes for better patient fit. Most of our male external catheters are made from silicone, a non-toxic and biocompatible material that eliminates the risks of latex-related skin irritation. Silicone catheters are also odor free and have greater air permeability than catheters made from other materials, including latex. Air permeability reduces skin irritation and damage from catheter use and thereby increases patient comfort. Our silicone catheters are transparent, permitting visual skin inspection without removal of the catheters and aiding proper placement of the catheters. Our catheters also have a kink-proof funnel design to ensure uninterrupted urine flow. The self-adhering technology and patented forward-placement of the adhesive simplifies application of the catheters and provides a strong bond to the skin for greater patient confidence and improved wear.

We also manufacture and sell male external catheters made from a proprietary non-latex, non-silicone material to certain private label customers. Certain of these catheters use the same self-adhesive technology as our silicone MECs. Like the silicone MECs, these non-silicone catheters eliminate the risk of latex reactions and latex-related skin irritations. The non-silicone catheters also are odor free.

We also market two models of latex male external catheters in the United Kingdom: the *Freedom®* and *Freedom Plus®* catheters. Through a distribution agreement with Coloplast A/S ("Coloplast") entered in June 2006, Coloplast supplies us with our requirement of latex male external catheters for sale in the United Kingdom.

Intermittent Catheters. Our *Personal Catheters®* are a line of disposable intermittent catheters manufactured from silicone. We produce the *Personal Catheters* in three lengths for male, female, and pediatric use and in multiple diameters. We produce four distinct versions of the *Personal Catheter*: the basic Standard *Personal*

Catheter, the Antibacterial *Personal Catheter*, the Hydrophilic *Personal Catheter* (along with a new UK-only brand, the *Hydrosil Discreet*) and the Antibacterial *HydroPersonal Catheter*. The Antibacterial *Personal Catheter* provides site-specific delivery of nitrofurazone, a drug that has been proven effective in reducing urinary tract infections. The Hydrophilic *Personal Catheter* and the *Hydrosil Discreet* become extremely slippery when moistened, providing a very low friction surface for ease and comfort during insertion and removal. The Antibacterial *HydroPersonal Catheter* combines these innovations to offer the most advanced intermittant catheter technology available today. All of the *Personal Catheter* designs are latex-free and PVC-free, eliminating the allergen, toxin or disposal concerns commonly associated with latex and PVC catheters.

FemSoft Insert. The *FemSoft Insert* is a disposable device for the management of stress urinary incontinence in active women. It is a soft, conformable urethral insert that assists the female urethra and bladder neck to control the involuntary loss of urine. The device can be simply inserted, worn and removed for voiding by most women. It requires no inflation, deflation, syringes or valving mechanisms.

The *FemSoft Insert* is a minimally invasive device that provides a patient with effective control of her urinary function and eliminates the need for pads or liners that can cause embarrassment, restrict mobility and compromise lifestyle. In addition, the soft, liquid-filled silicone membrane of the *FemSoft Insert* has been designed to conform to anatomical variations of the urethra and follow the movements of the urethra during normal activities, thereby reducing leakage without chafing or abrasion of the delicate tissues of the urethra.

The *FemSoft Insert* is a prescription device that requires a woman to visit her physician. The physician will fit the patient with the proper size and instruct the patient on proper application of the *FemSoft Insert*.

Acute Care Products

Foley Catheters. Our *RELEASE-NF Catheter* is a silicone Foley catheter that has been designed to reduce the incidence of hospital acquired UTI. Using patented technology, the *RELEASE-NF Catheter* incorporates nitrofurazone, an effective broad-spectrum antibacterial agent, into the structure of the catheter, permitting sustained release of a controlled dosage directly into the urinary tract to retard the onset of infection.

We also offer standard silicone Foley catheters in a two-lumen version for urinary drainage management and in a three-lumen version that also supports irrigation of the urinary tract. These Foley catheters are available in all adult and pediatric sizes. All of our silicone Foley catheters eliminate the risk of the allergic reactions and tissue irritation and damage associated with latex Foley catheters. Our standard Foley catheters are transparent which enables healthcare professionals to observe urine flow. Unlike the manufacturing processes used by producers of competing silicone Foley catheters, in which the balloon is made separately and attached by hand in a separate process involving gluing, our automated manufacturing processes allow us to integrate the balloon into the structure of the Foley catheter, resulting in a smoother, more uniform exterior that may help reduce irritation to urinary tissue.

Our Foley catheters are packaged sterile in single catheter strips or in procedural trays and sold under the *Rochester Medical* brand and under private label arrangements. In addition, we sell our Foley catheters in bulk under private label arrangements for packaging in kits with tubing, collection bags and other associated materials.

Technology

We use proprietary, automated manufacturing technologies and processes to manufacture continence care devices cost effectively. The production of our products also depends on our materials expertise and know-how in the formulation of silicone and advanced polymer products. Our proprietary liquid encapsulation technology enables us to manufacture innovative products, such as our *FemSoft Insert*, that have soft, conformable, liquid-filled reservoirs, which cannot be manufactured using conventional technologies. Using this liquid encapsulation technology, we can mold and form liquid encapsulated devices in a variety of shapes and sizes in an automated process. Our manufacturing technologies and materials know-how also allow us to incorporate a sustained release antibacterial agent into our products. We believe that our manufacturing technology is particularly well-suited to high unit volume production and that our automated processes enable cost-effective production. We further believe that our manufacturing and materials expertise, particularly our proprietary liquid encapsulation technology, may be applicable to a variety of other devices for medical applications. We plan to consider, commensurate with our

financial and personnel resources, future research and development activities to investigate opportunities provided by our technology and know-how.

We believe that our proprietary manufacturing processes, materials expertise, custom designed equipment and technical know-how allow us to simplify and further automate traditional catheter manufacturing techniques to reduce our manufacturing costs. In order to manufacture high quality products at competitive costs, we concurrently design and develop new products and the processes and equipment to manufacture them.

Marketing and Sales

To date, a significant portion of our revenues have been derived from sales of our MECs and standard Foley catheters to medical products companies for resale under brands owned by such companies. Private label arrangements are likely to continue to account for a significant portion of our revenues in the foreseeable future, particularly in non-United Kingdom international markets where we do not maintain a direct sales presence.

We sell our products in the United States under the *Rochester Medical* brand name through a nine-person direct sales force. Through our subsidiary, Rochester Medical Limited, we sell our products in the United Kingdom under the *Rochester Medical* brand name through a thirteen-person direct sales force. The primary markets for our products are distributors, extended care facilities and individual hospitals and healthcare institutions.

In November 2006, we announced we had been awarded a national Group Purchasing Contract for urological products from Premier Purchasing Partners, L.P. ("Premier"). The agreement became effective March 1, 2007. Premier is one of the largest Group Purchasing Organizations in the United States with over $27 billion in contract purchases per year. Its members include more than 1,500 hospital facilities and hundreds of other care sites. The contract includes our Foley catheters (including our infection control catheters), male external catheters, intermittent catheters, and urethral inserts.

In August 2007, we announced that Novation, LLC is awarding us an Innovative Technology Contract for its urological catheter products and related accessories, including our advanced infection control catheters. Novation provides contracting services to more than 2,500 members of VHA, Inc. and the University HealthSystem Consortium, or UHC, and nearly 9,000 members of Provista (formerly HPPI). The Innovative Technology Contract being awarded to us has a three year term from the effective date of September 1, 2007.

We rely on arrangements with medical product companies and independent distributors to sell our products in Europe and other international markets. These arrangements are conducted under the *Rochester Medical* brand name and under brands controlled by the medical product companies. International sales accounted for 57% and 49% of total sales in 2007 and 2006, respectively.

Manufacturing

We design and build custom equipment to implement our manufacturing technologies and processes. Our manufacturing facilities are located in Stewartville, Minnesota. We produce our Foley catheters on one production line and our MECs on other lines. We have constructed a separate manufacturing facility which houses our liquid encapsulation manufacturing operations, as well as our *FemSoft Insert* and intermittent catheter manufacturing lines.

We maintain a comprehensive quality assurance and quality control program, which includes documentation of all material specifications, operating procedures, equipment maintenance and quality control test methods. We have obtained ISO 13485 certification for our Foley catheter, male external catheter, intermittent catheter and *FemSoft Insert* production lines.

Our manufacturing facilities have been designed to accommodate the specialized requirements for the manufacture of medical devices, including the Food and Drug Administration's ("FDA") requirements for Quality System Regulation, or QSR.

Sources of Supply

We obtain certain raw materials and components for a number of our products from a sole supplier or limited number of suppliers. The loss of such a supplier or suppliers, or a material interruption of deliveries from such a supplier or suppliers, could have a material adverse effect on us. We believe that in most cases we have identified other potential suppliers. In the event that we have to replace a supplier, however, we may be required to repeat biocompatibility and other testing of our products using the material from the new supplier and may be required to obtain additional regulatory clearances.

Through a distribution agreement with Coloplast entered in June 2006, Coloplast supplies us with our requirement of latex male external catheters for sale in the United Kingdom under our newly acquired *Freedom®* and *Freedom Plus®* brands.

Research and Development

We believe that our ability to add new products to our existing continence care product lines is important to our future success. Accordingly, we are engaged in ongoing research and development to develop and introduce new products which provide additional features and functionality. In the future, consistent with market opportunities and our financial and personnel resources, we intend to perform clinical studies for other of our products in development.

Research and development expense for fiscal years 2007, 2006 and 2005 was $943,000, $760,000 and $730,000, respectively.

Competition

The continence care market is highly competitive. We believe that the primary competitive factors include price, product quality, technical capability, breadth of product line and distribution capabilities. Our ability to compete is affected by our product development and innovation capabilities, our ability to obtain regulatory clearances, our ability to protect the proprietary technology of our products and manufacturing processes, our marketing capabilities, and our ability to attract and retain skilled employees, to maintain current distribution relationships, to establish new distribution relationships and to secure participation in purchase contracts with group purchasing organizations. We believe that it is important to differentiate our products and broaden our product lines in order to attract large customers, such as distributors, dealers, institutions and home care organizations.

Our products compete with a number of alternative products and treatments for continence care. Our ability to compete with these alternative methods for urinary continence care depends on the relative market acceptance of alternative products and therapies and the technological advances in these alternative products and therapies. Any development of a broad-based and effective cure for a significant form of incontinence could have a material adverse effect on sales of continence care devices such as our products.

We compete directly for sales of continence care devices under our own *Rochester Medical* brand with larger, multi-product medical device manufacturers and distributors such as C.R. Bard, Inc., Unomedical, Kendall Covidan Healthcare Products Company, Hollister, Astra Tech AB and Coloplast. Many of the competitive alternative products or therapies are distributed by larger competitors including Johnson & Johnson Personal Products Company, Kimberly-Clark Corporation and Proctor & Gamble Company (for adult diapers and absorbent pads), and C.R. Bard, Inc. (for injectable materials). Many of our competitors, potential competitors and providers of alternative products or therapies have significantly greater financial, manufacturing, marketing, distribution and technical resources and experience than us. It is possible that other large healthcare and consumer products companies may enter this market in the future. Furthermore, academic institutions, governmental agencies and other public and private research organizations will likely continue to conduct research, seek patent protection and establish arrangements for commercializing products in this market. Such products may compete directly with our products.

Patents and Proprietary Rights

Our success may depend in part on our ability to obtain patent protection for our products and manufacturing processes, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. We may seek patents on certain features of our products and technology based on our analysis of various business considerations, such as the cost of obtaining a patent, the likely scope of patent protection and the benefits of patent protection relative to relying on trade secret protection. We also rely upon trade secrets, know-how and continuing technological innovations to develop and maintain our competitive position.

We hold 20 patents in the United States and a number of corresponding foreign patents that generally relate to certain of our catheters and devices and certain of our production processes. In addition, we have a number of pending United States and corresponding foreign patent applications. We may file additional patent applications for certain of our current and proposed products and processes in the future. In addition, we have entered into a Cross License Agreement with Coloplast related to certain patents held by each party. The cross licensing is for the purpose of avoidance of future infringement claims by each party.

There can be no assurance that our patents will be of sufficient scope or strength to provide meaningful protection of our products and technologies. The coverage sought in a patent application can be denied or significantly reduced before the patent is issued. In addition, there can be no assurance that our patents will not be challenged, invalidated or circumvented or that the rights granted thereunder will provide proprietary protection or commercial advantage to us.

Should attempts be made to challenge, invalidate or circumvent our patents in the U.S. Patent and Trademark Office and/or courts of competent jurisdiction, including administrative boards or tribunals, we may have to participate in legal or quasi-legal proceedings, to maintain, defend or enforce our rights in these patents. Any legal proceedings to maintain, defend or enforce our patent rights can be lengthy and costly, with no guarantee of success.

A claim by third parties that our current products or products under development allegedly infringe their patent rights could have a material adverse effect on us. We are aware that others have obtained or are pursuing patent protection for various aspects of the design, production and manufacturing of continence care products. The medical device industry is characterized by frequent and substantial intellectual property litigation, particularly with respect to newly developed technology. Intellectual property litigation is complex and expensive, and the outcome of such litigation is difficult to predict. Any future litigation, regardless of outcome, could result in substantial expense to us and significant diversion of the efforts of our technical and management personnel. An adverse determination in any such proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from such parties, if licenses to such rights could be obtained, and/or require us to cease using such technology. There can be no assurance that if such licenses were obtainable, they would be obtainable at costs reasonable to us. If forced to cease using such technology, there can be no assurance that we would be able to develop or obtain alternate technology. Additionally, if third party patents containing claims affecting our technology are issued and such claims are determined to be valid, there can be no assurance that we would be able to obtain licenses to such patents at costs reasonable to us, if at all, or be able to develop or obtain alternate technology. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing, using or selling certain of our products, which could have a material adverse effect on our business, financial condition and results of operations.

We also rely on proprietary manufacturing processes and techniques, materials expertise and trade secrets applicable to the manufacture of our products. We seek to maintain the confidentiality of this proprietary information. There can be no assurance, however, that the measures taken by us will provide us with adequate protection of our proprietary information or with adequate remedies in the event of unauthorized use or disclosure. In addition, there can be no assurance that our competitors will not independently develop or otherwise gain access to processes, techniques or trade secrets that are similar or superior to ours. Finally, as with patent rights, legal action to enforce trade secret rights can be lengthy and costly, with no guarantee of success.

Government Regulation

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA and corresponding foreign agencies. In the United States, the medical devices manufactured and sold by us are subject to laws and regulations administered by the FDA, including regulations concerning the prerequisites to commercial marketing, the conduct of clinical investigations, compliance with QSR and labeling.

A manufacturer may seek from the FDA market authorization to distribute a new medical device by filing a 510(k) Premarket Notification to establish that the device is "substantially equivalent" to medical devices legally marketed in the United States prior to the Medical Device Amendments of 1976. A manufacturer may also seek market authorization for a new medical device through the more rigorous Premarket Approval ("PMA") application process, which requires the FDA to determine that the device is safe and effective for the purposes intended. All of our marketed products have received FDA marketing authorization pursuant to 510(k) notifications or PMA approval.

We are also required to register with the FDA as a medical device manufacturer. As such, our manufacturing facilities are inspected on a routine basis for compliance with QSR. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities. As a medical device manufacturer, we are further required to comply with FDA requirements regarding the reporting of adverse events associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. FDA regulations also govern product labeling and can prohibit a manufacturer from marketing an approved device for unapproved applications. If the FDA believes that a manufacturer is not in compliance with the law, it can institute enforcement proceedings to detain or seize products, issue a recall, enjoin future violations and assess civil and criminal penalties against the manufacturer, its officers and employees.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA approval. These differences may affect the efficiency and timeliness of international market introduction of our products. For countries in the European Union ("EU"), medical devices must display a CE mark before they may be imported or sold. In order to obtain and maintain the CE mark, we must comply with the Medical Device Directive and pass an initial and annual facilities audit inspections to ISO 13485 standards by an EU inspection agency. We have obtained ISO 13485 quality system certification for the products we currently distribute into the EU. In order to maintain certification, we are required to pass annual facilities audit inspections conducted by EU inspectors.

In addition, international sales of medical devices manufactured in the United States that have not been approved by the FDA for marketing in the United States are subject to FDA export requirements. These require that we obtain documentation from the medical device regulatory authority of the destination country stating that sale of the medical device is not in violation of that country's medical device laws, and, under some circumstances, may require us to apply to the FDA for permission to export a device to that country.

Third Party Reimbursement

In the United States, healthcare providers that purchase medical devices generally rely on third party payors, such as Medicare, Medicaid, private health insurance plans and managed care organizations, to reimburse all or a portion of the cost of the devices. The Medicare program is funded and administered by the federal government, while the Medicaid program is jointly funded by the federal government and the states, which administer the program under general federal oversight. We believe our currently marketed products are generally eligible for coverage under these third party reimbursement programs. In some instances, we have received Medicare reimbursement for the *FemSoft Insert*, and several private health insurance plans also offer this reimbursement. The competitive position of certain of our products may be partially dependent upon the extent of reimbursement for our products.

In foreign countries, the policies and procedures for obtaining third party payment of reimbursement for medical devices vary widely. Compliance with such procedures may delay or prevent the eligibility of our branded and/or private label products for reimbursement, and have an adverse effect on our ability to sell our branded or private label products in a particular foreign country.

Private Label Distribution Agreements

We supply a number of medical product companies with products on a private label basis. Our practice has been to enter into written agreements with these distributors of our products.

In June 2006, we entered into a new Private Label Distribution Agreement with Coloplast under which we will supply silicone MECs to Coloplast, which will be sold under Coloplast's brands worldwide, excluding the United Kingdom. In December 2006, we entered into a new Private Label Agreement for supply of MECs to Hollister for sale under the Hollister brand worldwide, excluding the United Kingdom.

In two instances to date, we have entered into agreements with distributors providing for certain exclusive marketing and distribution rights. In fiscal 2002, we entered into an agreement with Coloplast granting Coloplast exclusive marketing and distribution rights with respect to our *Release-NF* Foley catheters in certain geographic areas. This agreement was terminated by mutual consent in fiscal 2007. In fiscal 2003, we entered into an agreement with Hollister granting exclusive marketing and distribution rights in certain geographic areas with respect to our hydrophilic intermittent catheters. The agreement with Hollister was amended in December 2006, and continues through December 31, 2008, although on a non-exclusive basis.

Environmental Matters

We and the industry in which we compete are subject to environmental laws and regulations concerning emissions to the air, discharges to waterways and the generation, handling, storage, transportation, treatment and disposal of waste materials. Our policy is to comply with all applicable environmental, health and safety laws and regulations. These laws and regulations are constantly evolving and it is difficult to predict accurately the effect they will have on us in the future. Compliance with applicable environmental regulations and controls has not had, nor are they expected to have in the future, any material impact on our capital expenditures, earnings or competitive position.

Employees

As of September 30, 2007, we employed 268 full-time employees, of whom 198 were in manufacturing, and the remainder in marketing and sales, research and development and administration. We are not a party to any collective bargaining agreement and believe our employee relations are good.

Executive Officers of the Registrant

Our executive officers are as follows:

Name	Age	Position
Anthony J. Conway	63	Chairman of the Board, Chief Executive Officer, President and Secretary
David A. Jonas	43	Chief Financial Officer and Treasurer
Philip J. Conway	51	Vice President, Production Technologies
Dara Lynn Horner	49	Vice President, Marketing
Martyn R. Sholtis	48	Corporate Vice President

Anthony J. Conway, one of our founders, has served as our Chairman of the Board, Chief Executive Officer, President and Secretary since May 1988. In addition to his duties as Chief Executive Officer, Mr. Anthony Conway actively contributes to our research and development and design activities. From 1979 to March 1988, he was President, Secretary and Treasurer of Arcon Corporation, a company that he co-founded with Philip J. Conway in 1979 to develop, manufacture and sell latex-based male external catheters and related medical devices. Prior to

founding Arcon, Mr. Anthony Conway worked for twelve years for International Business Machines Corporation in various research and development capacities. Mr. Anthony Conway is one of the named inventors on numerous patent applications that have been assigned to us, of which to date 20 have resulted in issued U.S. patents and 32 have resulted in issued foreign patents.

David A. Jonas has served as our Treasurer since November 2000 and as our Chief Financial Officer since May 2001. From June 1, 1998 until May 2001, Mr. Jonas served as our Controller. From August 1999 until October 2001, Mr. Jonas served as our Director of Operations and had principal responsibility for our operational activities. Since November 2000, Mr. Jonas has had principal responsibility for our financial activities. Prior to joining us, Mr. Jonas was employed in various financial, financial management and operational management positions with Polaris Industries, Inc. from January 1989 to June 1998. Mr. Jonas holds a BS degree in Accounting from the University of Minnesota and is a certified public accountant currently under a "non-active" status.

Philip J. Conway, one of our founders, has served as our Vice President of Production Technologies since August 1999. From 1988 to July 1999, Mr. Philip Conway served as our Vice President of Operations. Mr. Philip Conway is responsible for plant design as well as new product and production processes, research, design and development activities. Since November 2001, he has had principal responsibility for our operational activities. From 1979 to March 1988, Mr. Philip Conway served as Plant and Production Manager of Arcon Corporation. Prior to joining Arcon, Mr. Philip Conway was employed in a production supervisory capacity by AFC Corp., a manufacturer and fabricator of fiberglass, plastics and other composite materials. He is one of the named inventors on numerous patent applications that have been assigned to us, of which to date 20 have resulted in issued U.S. patents and 32 have resulted in issued foreign patents.

Dara Lynn Horner joined us in November 1998 and serves as our Vice President of Marketing. From November 1998 until November 1999, Ms. Horner served as Marketing Director for our *FemSoft Insert* product line. Ms. Horner has principal responsibility for management of our marketing activities. From 1990 until joining us in 1998, Ms. Horner was employed by Lake Region Manufacturing, Inc., a medical device manufacturer, most recently as Marketing Director.

Martyn R. Sholtis joined us in April 1992 and serves as our Corporate Vice President. Mr. Sholtis is responsible for all sales and for corporate business development activities. From 1985 to 1992, Mr. Sholtis was employed by Sherwood Medical, a company that manufactured and sold a variety of disposable medical products including urological catheters, most recently as Regional Sales Manager for the Nursing Care Division.

Messrs. Anthony J. Conway, Philip J. Conway and Peter R. Conway, a director of the company, are brothers.

Recent Developments

On November 6, 2006, we announced we had been awarded a national Group Purchasing Contract for urological products from Premier Purchasing Partners, L.P. The agreement became effective March 1, 2007. Premier is one of the largest Group Purchasing Organizations in the United States with over $27 billion in contract purchases per year. Its members include more than 1,500 hospital facilities and hundreds of other care sites. The contract includes our Foley catheters (including its infection control catheters), MECs, intermittent catheters, and urethral inserts.

On November 20, 2006, we announced that we had reached a settlement with Premier, Inc. and Premier Purchasing Partners, L.P. with respect to the lawsuit we initiated in February 2004 against certain GPOs and individual defendants alleging anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters. Under the settlement agreement, Premier paid us $8,825,000 (net $5,155,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit. On December 14, 2006, we announced we had reached a settlement with C.R. Bard, Inc., whereby C.R. Bard, Inc. paid us $49,000,000 (net $33,450,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit.

On December 11, 2006, we announced we had signed a new Private Label Agreement for supply of MECs to Hollister Incorporated for sale under the Hollister brand worldwide, excluding the United Kingdom, and also announced that we amended our 2003 OEM/Private Label Agreement. The two companies also agreed to terminate the Common Interest and Defense Agreement which we entered into in September, 2004 for the defense of our

Hydrophilic Intermittent catheter technology with respect to the patent infringement action in the United Kingdom between Coloplast A/S and Hollister. We have agreed with Hollister to release each other from any claims under the Common Interest and Defense Agreement. In particular, we will not be required to pay any additional legal fees under the terminated agreement.

On August 6, 2007, we announced that we had reached a settlement with Novation LLC with respect to the lawsuit described above. Under the settlement agreement, Novation is awarding us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced Infection Control catheters, and was dismissed from the lawsuit. The Innovation Technology Contract has a three-year term from the effective date of September 1, 2007.

As discussed in Item 3. Legal Proceedings, our litigation alleging anti-competitive conduct continues against Tyco, and is scheduled for trial in February 2008.

In September 2007, we announced the publication in the September issue of "Annals of Internal Medicine" of results of a randomized, double-blind, controlled clinical study involving 212 adult patients at Denmark's Copenhagen Trauma Center. The study concluded nitrofurazone-impregnated urinary catheters reduced the incidence of catheter-associated bacteriuria and funguria in adult trauma patients, reducing the need to change or prescribe new antimicrobial therapy. The nitrofurazone-impregnated urinary catheters used in the study were manufactured by Rochester Medical. The control catheter was an all-silicone Foley catheter.

Information Available on Our Website

Our corporate office is located at One Rochester Medical Drive, Stewartville, Minnesota 55976, and our telephone number is (507) 533-9600. We make our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K available free of charge through our website, at www.rocm.com, as soon as reasonably practicable after we electronically file such material with (or furnish such material to) the Securities and Exchange Commission. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be part of this Form 10-K.

ITEM 1A. Risk Factors

Our business, financial condition or results of operations could be materially adversely affected by any of the risks and uncertainties described below. Additional risks not presently known to us, or that we currently deem immaterial, may also impair our business, financial condition or results of operations.

A significant portion of our revenues come from a small number of customers

We depend on a relatively small number of customers for a significant portion of our net sales. Our five largest private label customers in fiscal 2007 represented approximately 40% of our total net sales. Because our larger private label customers typically purchase products in relatively large quantities at a time, our financial performance can fluctuate from quarter to quarter depending upon the timing of their purchases. We expect to continue to depend upon a relatively small number of customers for a significant percentage of our net sales. Because our major customers represent such a large part of our business, the loss of any of our major customers could negatively impact our business.

Our major customers may not continue to purchase products from us at current levels or at all. In the past, we have lost customers due to our customers' changes in technology preferences, customers' shifting production of products to internal facilities and the acquisition of our customers. We may lose customers in the future for similar reasons. We may not be able to expand our customer base to make up any sales shortfalls if we lose a major customer. Our attempt to diversify our customer base and reduce our reliance on particular customers may not be successful.

We depend on private label sales arrangements and third party distributors for a significant portion of our revenues, the loss of one or more of which could reduce our future sales revenue

A significant portion of our net sales to date have depended on our ability to provide products that meet the requirements of medical product companies that resell or distribute our products, and on the sales and marketing efforts of such entities. Arrangements with these entities are likely to continue to be a significant portion of our revenues in the future. There can be no assurance that our purchasers and distributors will be able to successfully market and sell our products, that they will devote sufficient resources to support the marketing of any of our products, that they will market any of our products at prices which will permit such products to develop, achieve, or sustain market acceptance, or that they will not develop alternative sources of supply. The failure of our purchasers and distributors to continue to purchase products from us at levels reasonably consistent with their prior purchases or to effectively market our products could significantly reduce our future sales revenue.

Our products may not succeed in the market

We have several products, including the antibacterial hydrophilic and antibacterial hydro intermittent catheters, the *RELEASE-NF Catheter*, and the *FemSoft Insert*, that represent new methods and improvements for urinary continence care. There can be no assurance that these products will gain any significant degree of market acceptance among physicians, healthcare payors and patients. Market acceptance of these products, if it occurs, may require lengthy hospital evaluations and/or the training of numerous physicians and clinicians, which could delay or dampen any such market acceptance. Moreover, approval of third party reimbursement for our products, competing products or alternative medical treatments, and our pricing policies will be important factors in determining market acceptance of these products. Any of the foregoing factors, or other factors, could limit or detract from market acceptance of these products. Insufficient market acceptance of these products could impact future sales revenue and have a material adverse effect on our business, financial condition and results of operations.

We may not succeed in establishing a separate brand identity for our Rochester Medical brand products

Our success will depend on our ability to overcome established market positions of competitors and to establish our own market presence under the *Rochester Medical* brand name. One of the challenges facing us in this respect is our ability to compete with companies that offer a wider array of products to hospitals and medical care institutions, distributors and end users. In addition, we have been unsuccessful until recently in competing in the Group Purchasing Organization (GPO) market, where organizations such as hospitals, rehabilitation centers and acute care facilities acquire products not directly from manufacturers, but rather from distributors where pricing is determined under agreements between those distributors and GPOs. In November 2006, we announced we had been awarded a national GPO contract for urological products from Premier Purchasing Partners, L.P., one of the largest GPOs in the United States with over $27 billion in contract purchases per year. The contract includes our Foley catheters (including its infection control catheters), male external catheters, intermittent catheters, and urethral inserts. In August 2007, we announced that Novation, LLC is awarding us an Innovative Technology Contract for its urological catheter products and related accessories, including our advanced infection control catheters. There can be no assurance, however, that these contracts will generate significant sales, that the contracts will be renewed beyond their initial terms, or that contracts with other GPOs will follow. We may also find it difficult to sell our products due to the limited recognition of our brand name.

In February 2004, we brought suit against certain GPOs and individual defendants alleging anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters, and seek an unspecified amount of damages and injunctive and other relief. In November 2006, we announced that we had reached a settlement with Premier, whereby Premier paid us $8,825,000 (net $5,155,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit. In December 2006, we announced that we had reached a settlement with C.R. Bard, Inc., whereby C.R. Bard paid us $49,000,000 (net $33,450,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit. In August 2007, we announced that we had reached a settlement with Novation LLC, whereby Novation is awarding us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced Infection Control catheters, and was dismissed from the lawsuit. The litigation continues against Tyco, which is scheduled for

trial in February 2008. There can be no assurance that we will be successful in the lawsuit against the remaining defendants.

We face significant competition in the market for urinary continence products

The medical products market in general is, and the markets for urinary continence care products in particular are, highly competitive. Many of our competitors have greater name recognition than us and offer well known and established products, some of which are less expensive than our products. As a result, even if we can demonstrate that our products provide greater ease of use, lifestyle improvement or beneficial effects on medical outcomes over the course of treatment, we may not be successful in capturing a significant share of the market. In addition, many of our competitors offer broader product lines than us, which may be a competitive advantage in obtaining contracts with GPOs, and may adversely affect our ability to obtain contracts with such GPOs. Additionally, many of our competitors have substantially more marketing and sales experience than us and substantially larger sales forces and greater resources to devote to such efforts. There can be no assurance that we will be able to compete successfully against such competitors.

Our products may become obsolete if we are unable to anticipate and adapt to new treatments or techniques

Urinary continence care can be managed with a variety of alternative medical treatments and management products or techniques, including adult diapers and absorbent pads, surgery, behavior therapy, pelvic muscle exercise, implantable devices, injectable materials and other medical devices. Manufacturers of these products or techniques are engaged in research to develop more advanced versions of current products and techniques. Many of the companies that are engaged in such development work have substantially greater capital resources than us and greater expertise than us in research, development and regulatory matters. There can be no assurance that our products will be able to compete with existing or future alternative products, techniques or therapies, or that advancements in existing products, techniques or therapies will not render our products obsolete.

We have a limited history of profitability and may experience future losses

We have generated only limited revenues to date and prior to fiscal 2003, experienced net losses since our inception. Net income for the fiscal years ended September 30, 2007, 2006, 2005, 2004 and 2003 was $34,050,000 (which included approximately $31,000,000 from lawsuits net of taxes), $1,959,000, $934,000, $747,000 and $330,000, respectively, while the net loss for the fiscal year ended September 30, 2002 was $1.4 million. A substantial portion of the expenses associated with our manufacturing facilities are fixed in nature (i.e. depreciation) and will reduce our operating margin until such time, if ever, as we are able to increase utilization of our capacity through increased sales of our new products. As a result, there can be no assurance that we will ever generate substantial revenues or sustain profitability. Although we achieved profitability in fiscal years 2003 through 2007, we cannot be certain that we will be able to sustain or increase profitability on a quarterly or annual basis.

Our products and manufacturing activities are subject to extensive governmental regulation that could prevent us from selling our products or introducing new and/or improved products in the United States or internationally

Our products, product development activities and manufacturing processes are subject to extensive regulation by the FDA and by comparable agencies in foreign countries. In the United States, the FDA regulates the introduction of medical devices as well as manufacturing, labeling and record keeping procedures for such products. The process of obtaining marketing clearance for new medical products from the FDA can be costly and time consuming, and there can be no assurance that such clearance will be granted timely, if at all, for our products in development, or that FDA review will not involve delays that would adversely affect our ability to commercialize additional products or to expand permitted uses of existing products. Even if regulatory clearance to market a product is obtained from the FDA, this clearance may entail limitations on the indicated uses of the product. Marketing clearance can also be withdrawn by the FDA due to failure to comply with regulatory standards or the occurrence of unforeseen problems following initial clearance.

We may be required to make further filings with the FDA under certain circumstances, such as the addition of product claims or product reformulation. The FDA could also limit or prevent the manufacture or distribution of our products and has the power to require the recall of such products. FDA regulations depend heavily on administrative interpretation, and there can be no assurance that future interpretation made by the FDA or other regulatory bodies, which may have retroactive effect, will not adversely affect us. The FDA and various state agencies inspect us and our facilities from time to time to determine whether we are in compliance with regulations relating to medical device manufacturing companies, including regulations concerning design, manufacturing, testing, quality control and product labeling practices. A determination that we are in material violation of such regulations could lead to the imposition of civil penalties, including fines, product recalls, product seizures, or, in extreme cases, criminal sanctions.

A portion of our revenues are dependent upon sales of our products outside the United States. Foreign regulatory bodies have established varying regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. We rely on our third-party foreign distributors to comply with certain foreign regulatory requirements. The inability or failure of us or such foreign distributors to comply with varying foreign regulations or the imposition of new regulations could restrict the sale of our products internationally and thereby adversely affect our business, financial condition and results of operations.

Our success may depend on the ability of healthcare providers to achieve adequate levels of third-party reimbursement

In the United States, healthcare providers that purchase medical devices generally rely on third party payors, such as Medicare, Medicaid, private health insurance plans and managed care organizations, to reimburse all or a portion of the cost of the devices. Third party payors are increasingly challenging the pricing of medical products and procedures they consider unnecessary, inappropriate, not cost effective, experimental or used for a non-approved indication. Even if a medical device is eligible for reimbursement, the level of reimbursement may not be adequate to enable us to achieve or maintain market acceptance of our products or maintain price levels that exceed our costs of developing and manufacturing our products.

We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on us. Reforms may include mandated basic health care benefits, limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, greater reliance on prospective payment systems, the creation of large insurance purchasing groups and fundamental changes to the health care delivery system. We anticipate that Congress and state legislatures will continue to review and assess alternative health care delivery systems and payment methodologies. We cannot predict whether any reform proposals will be adopted or what impact they may have on us.

Reimbursement systems in international markets vary significantly by country and by region within some countries. Many international markets have government managed health care systems that control reimbursement for new devices and procedures. In most international markets, there are private insurance systems as well as government managed systems. We cannot assure you that reimbursement for our products will be available in international markets under either government or private reimbursement systems.

We depend on certain key personnel, the loss of whom could harm our business

If we are unable to attract, train and retain highly-skilled technical, managerial, sales and marketing personnel, we may be at a competitive disadvantage and unable to develop new products or increase revenue. We may grant large numbers of stock options to attract and retain personnel, which could be highly dilutive to our shareholders. The failure to attract, train, retain and effectively manage employees could negatively impact our research and development and sales efforts. In particular, the loss of sales personnel could lead to lost sales opportunities because it can take several months to hire and train replacement sales personnel. Uncertainty created by turnover of key employees could adversely affect our business, operating results and stock price.

We depend on a few suppliers for key components, making us vulnerable to supply shortages and price fluctuation

We obtain certain raw materials and components for a number of our products from a sole supplier or limited number of suppliers; we have no long-term supply contracts with any of our vendors. While it is our goal to have multiple sources to procure certain key components, in some cases it is not economically practical or feasible to do so. To mitigate this risk, we maintain an awareness of alternate supply sources that could provide our currently single-sourced raw materials or components with minimal or no modification to the current version of our products, practice supply chain management, maintain safety stocks of critical raw materials and components and have arrangements with our key suppliers to manage the availability of critical components. Despite these efforts, if our suppliers are unable to provide us with an adequate supply of raw materials or components in a timely manner, or if we are unable to locate qualified alternate suppliers for components at a reasonable cost, the cost of our products would increase, the availability of our products to our customers would decrease and our ability to generate revenues could be materially limited. Additionally, in the event that we have to replace a supplier, we may be required to repeat biocompatibility and other testing of our products using the material from the new supplier and may be required to obtain additional regulatory clearances.

All of our manufacturing operations are conducted at a single industrial park; therefore, any disruption at our existing facilities could substantially affect our business

We manufacture our products at one industrial park using certain specialized equipment. Although we have contingency plans in effect for certain natural disasters, as well as other unforeseen events that could damage our facilities or equipment, any such events could materially interrupt our manufacturing operations. In the event of such an occurrence, we have business interruption insurance to cover lost revenues and profits. However, such insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with existing customers created by an inability to produce our products.

We depend on patents and proprietary rights, which we may not be able to protect

Our success may depend in part on our ability to obtain patent protection for our products and manufacturing processes, to preserve our trade secrets, and to operate without infringing the proprietary rights of third parties. The validity and breadth of claims covered in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. No assurance can be given that the scope of any patent protection under our current patents, or under any patent we might obtain in the future, will exclude competitors or provide competitive advantages to us; that any of our patents will be held valid if subsequently challenged; or that others will not claim rights in or ownership of the patents and other proprietary rights held by us. There can be no assurance that our technology, current or future products or activities will not be deemed to infringe upon the rights of others. Furthermore, there can be no assurance that others have not developed or will not develop similar products or manufacturing processes, duplicate any of our products or manufacturing processes, or design around our patents. We also rely upon unpatented trade secrets to protect our proprietary technology, and no assurance can be given that others will not independently develop or otherwise acquire substantially equivalent technology or otherwise gain access to our proprietary technology or disclose such technology or that we can ultimately protect meaningful rights to such unpatented proprietary technology.

We may face intellectual property infringement claims that would be costly to resolve

The medical device industry is characterized by frequent and substantial intellectual property litigation, particularly with respect to newly developed technology. Litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us, or to determine the ownership, scope or validity of the proprietary rights of us and others. Intellectual property litigation is complex and expensive, and the outcome of such litigation is difficult to predict. Any such litigation, regardless of outcome, could result in substantial expense to us and significant diversion of the efforts of our technical and management personnel. As a result, a claim by a third party that our current products or products in development allegedly infringe its patent rights could have a material adverse effect on us. Moreover, an adverse determination in any such proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from such parties, if licenses to such

rights could be obtained, and/or require us to cease using such technology. If third party patents containing claims affecting our technology were issued and such claims were determined to be valid, there can be no assurance that we would be able to obtain licenses to such patents at costs reasonable to us, if at all, or be able to develop or obtain alternate technology. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing, using or selling certain of our products, which could have a material adverse effect on our business, financial condition and results of operations.

We may face product liability claims that could result in costly litigation and significant liabilities

The medical products industry is subject to substantial product liability litigation, and we face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects to a patient. Any such claims could have a material adverse effect on us, including on market acceptance of our products. We maintain general insurance policies that include coverage for product liability claims. The policies are limited to an aggregate maximum of $6 million per product liability claim, with an annual aggregate limit of $7 million under the policies. We have an additional $4 million of coverage per product liability claim and annual aggregate limit related to the United Kingdom. We may require increased product liability coverage as new products are developed and commercialized. There can be no assurance that liability claims will not exceed the coverage limits of our policies or that adequate insurance will continue to be available on commercially reasonable terms, if at all. A product liability claim or other claim with respect to uninsured liabilities or in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

International operations will expose us to additional risks

We are marketing and will continue to market and sell our products either through a direct sales force or through distributors in international markets, subject to our receipt of the requisite foreign regulatory approvals. We have distribution arrangements with approximately 10 distributors in international markets. We cannot assure you that international distributors for our products will devote adequate resources to selling and servicing our products.

Our international sales are subject to several risks, including:

- the ability of our independent distributors to market and sell our products;
- our ability to identify new independent distributors in international markets where we do not currently have distributors;
- the impact of recessions in economies outside the United States;
- greater difficulty in collecting accounts receivable and longer collection periods;
- unexpected changes in regulatory requirements, tariffs or other trade barriers;
- weaker intellectual property rights protection in some countries;
- potentially adverse tax consequences; and
- political and economic instability.

The occurrence of any of these events could seriously harm our future international sales and our ability to successfully commercialize our products in international markets, thereby limiting our growth and revenues.

Our business is also expected to subject us and our representatives, agents and distributors to laws and regulations of the foreign jurisdictions in which we operate or our products are sold. We may depend on foreign distributors and agents for compliance and adherence to foreign laws and regulations.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance requirements

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in 2007, we must perform system and

process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. Moreover, if our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

In addition, the Sarbanes-Oxley Act, together with new rules subsequently implemented by the Securities and Exchange Commission and Nasdaq, have imposed various new requirements on public companies, including requiring certain corporate governance practices. These rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We may be unable to meet our future capital requirements

We believe our existing resources and anticipated cash flows from operations will be sufficient to satisfy our capital needs for the foreseeable future. However, our actual liquidity and capital requirements will depend on numerous factors, including the costs, method and timing of expansion of sales and marketing activities and manufacturing capacity; the amount of revenues from sales of our existing and new products, including hydrophilic and antibacterial intermittent catheters, the *RELEASE-NF Catheter* and the *FemSoft Insert*; changes in, termination of, and the success of, existing and new distribution arrangements; the cost of maintaining, enforcing and defending patents and other intellectual property rights; competing technological and market developments; developments relating to regulatory and third party reimbursement matters; the cost and progress of our research and development efforts; opportunities for growth through acquisition, joint venture or other business combinations, if any; and other factors. In the event that additional financing is needed, we may seek to raise additional funds through public or private financing, collaborate relationships or other arrangements. Any additional equity financing may be dilutive to shareholders, and debt financing, if available, may involve significant restrictive covenants. Failure to raise capital when needed could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that such financing, if required, will be available on terms satisfactory to us, if at all.

ITEM 1B. Unresolved Staff Comments

None.

ITEM 2. Properties

Our administrative offices and liquid encapsulation manufacturing facilities occupy a 66,000 square foot manufacturing and office facility on a 33-acre site owned by us and located in an industrial park in Stewartville, Minnesota. Our male external catheter and Foley catheter manufacturing facilities consists of a 34,000 square foot manufacturing and office building located on a nearby 3.5 acre site owned by us in the same industrial park. We also own a 13,000 square foot office building/warehouse in Lancing, England. Based on present plans, we believe that our current facilities, which are in good operating condition, will be adequate to meet our anticipated needs for at least the next several years.

ITEM 3. Legal Proceedings

We are plaintiff in a lawsuit titled Rochester Medical Corporation vs. C.R. Bard, Inc.; Tyco International (US), Inc.; Tyco Health Care Group, L.P.; Novation LLC; VHA, Inc.; Premier, Inc.; and Premier Purchasing Partners, in the United States District Court for the Eastern District of Texas, Civil Action No. 504-CV-060. This suit alleges anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters, and seeks an unspecified amount of damages and injunctive and other relief.

On November 20, 2006, we announced that we had reached a settlement with Premier, Inc. and Premier Purchasing Partners, L.P. with respect to the lawsuit. Under the settlement agreement, Premier paid us $8,825,000 (net $5,155,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit.

On December 14, 2006, we announced we had reached a settlement with C.R. Bard, Inc., whereby C.R. Bard, Inc. paid us $49,000,000 (net $33,450,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit.

On August 6, 2007, we announced that we had reached a settlement with Novation LLC with respect to the lawsuit. Under the settlement agreement, Novation is awarding us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced Infection Control catheters, and was dismissed from the lawsuit. The Innovation Technology Contract has a three-year term from the effective date of September 1, 2007. The litigation continues against Tyco, which is scheduled for trial in February 2008.

We are not subject to any other pending or threatened litigation other than routine litigation arising in the ordinary course of business, none of which is expected to have a material adverse effect on our financial condition, results of operations or cash flows.

ITEM 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of security holders during the fourth quarter ended September 30, 2007.

PART II

ITEM 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Stock Listing and Prices

Our common stock is quoted on the Nasdaq Global Market under the symbol ROCM. The following table sets forth, for the periods indicated, the range of high and low last sale prices for our common stock as reported by the Nasdaq Global Market. On October 31, 2006, our Board of Directors declared a two-for-one stock split of our common stock. As a result of the stock split, on November 17, 2006, shareholders received one additional common share for each common share held on the record date of November 14, 2006. All share and per share amounts in this Form 10-K have been restated to reflect our stock split.

	High	Low
Fiscal 2006		
First Quarter	$ 5.10	4.55
Second Quarter	6.37	5.08
Third Quarter	7.75	6.22
Fourth Quarter	8.12	7.05
Fiscal 2007		
First Quarter	$12.58	7.75
Second Quarter	22.78	12.46
Third Quarter	29.48	14.57
Fourth Quarter	19.04	13.70

Repurchases of Equity Securities

In December 1999, the Board of Directors authorized a stock repurchase program. Up to two million shares of our outstanding common stock may be repurchased under the program. Purchases may be made from time to time at prevailing prices in the open market and through other customary means. No time limit has been placed on the duration of the stock repurchase program and it may be conducted over an extended period of time as business and market conditions warrant. We also may discontinue the stock repurchase program at any time. The repurchased

shares will be available for reissuance pursuant to employee stock option plans and for other corporate purposes. We intend to fund such repurchases with currently available funds. During fiscal 2007, we did not repurchase any shares of common stock pursuant to this program.

Pursuant to our employee stock plans relating to the grant of employee stock options and restricted stock awards, we have granted and may in the future grant employee stock options to purchase shares of our common stock for which the purchase price may be paid by means of delivery to us by the optionee of shares of our common stock that are already owned by the optionee (at a value equal to market value on the date of the option exercise). In December 2006, two of our executive officers and one of our directors tendered an aggregate of 41,340 shares of our common stock with a fair market value of $485,750 in order to exercise options to purchase 56,000 shares.

Holders

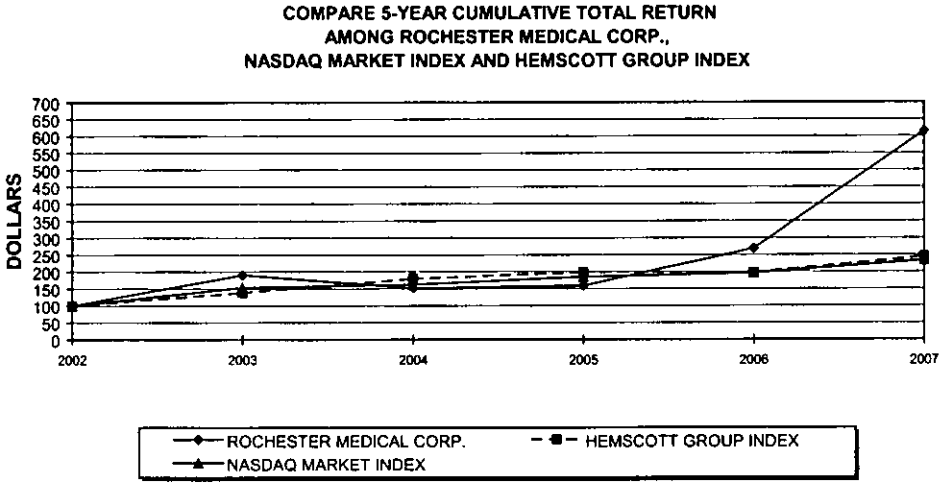
As of November 1, 2007, we had 124 shareholders of record. Such number of record holders does not reflect shareholders who beneficially own common stock in nominee or street name.

Dividends

We have paid no cash dividends on our common stock, and we do not intend to pay cash dividends on our common stock in the foreseeable future.

Stock Performance Graph

The following graph compares the yearly percentage changes in the cumulative total shareholder return on our common stock with the cumulative total return on the Nasdaq Market Index and the Hemscott Group Medical Instruments and Supplies Index ("MG Index") during the five fiscal years ended September 30, 2007. The comparison assumes $100 was invested on September 29, 2002 in our common stock and in each of the foregoing indices and assumes reinvestment of dividends. We did not pay any dividends during any period presented. Shareholder returns over the indicated period should not be considered indicative of future shareholder returns.



ITEM 6. Selected Financial Data

The following selected financial data of Rochester Medical Corporation as of September 30, 2007 and 2006 and for the three fiscal years ended September 30, 2007, 2006 and 2005 are derived from, and should be read together with, our consolidated financial statements audited by McGladrey & Pullen LLP, independent auditors, included elsewhere in this Form 10-K. The following selected financial data as of September 30, 2005, 2004 and 2003 and for the fiscal years ended September 30, 2004 and 2003 are derived from audited financial statements not included herein. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," the Consolidated Financial Statements and Notes thereto and other financial information included elsewhere in this Form 10-K.

	Fiscal Years Ended September 30,				
	2007	2006	2005	2004	2003
	(In thousands, except for per share data)				
Net sales	$32,663	$21,666	$15,942	$15,011	$14,655
Cost of sales	15,619	13,057	10,330	9,615	9,574
Gross profit	17,044	8,609	5,612	5,396	5,081
Operating expenses:					
Marketing and selling	6,490	3,109	2,398	2,176	2,225
Research and development	943	760	730	706	875
General and administrative	6,743	3,345	2,127	1,857	1,809
Total operating expenses	14,176	7,214	5,255	4,739	4,909
Income from operations	2,868	1,395	357	657	172
Other income	38,855	—	—	—	—
Interest income (expense), net	775	(108)	124	90	158
Net income before income tax	42,498	1,287	481	747	330
Income tax benefit (expense)	(8,448)	672	454	—	—
Net income	$34,050	$ 1,959	$ 935	$ 747	$ 330
Net income per common share — basic	$ 2.97	$ .18	$ .09	$ .07	$ .03
Net income per common share — diluted	$ 2.77	$ .17	$ .08	$ .07	$ .03
Weighted average number of common shares outstanding — basic	11,450	11,068	10,932	10,868	10,760
Weighted average number of common shares outstanding — diluted	12,272	11,666	11,430	11,374	11,308

	As of September 30,				
	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$37,137	$ 2,907	$ 6,416	$ 5,872	$ 5,966
Working capital	46,325	7,664	12,671	11,119	10,398
Total assets	75,495	35,952	22,209	21,384	21,125
Long-term debt and capital lease obligations	6,066	7,563	98	172	267
Retained earnings (accumulated deficit)	13,964	(20,086)	(22,045)	(22,979)	(23,726)
Total shareholders' equity	$64,509	$ 23,097	$ 20,288	$ 18,888	$ 18,142

No dividends were declared or paid in any year from 2003 to 2007.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Our Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the narrative description of our business in Item 1 of Part I of our Annual Report on Form 10-K and our Consolidated Financial Statements, accompanying Notes and other information listed in the accompanying Financial Table of Contents.

Overview

We develop, manufacture and market a broad line of innovative, technologically enhanced PVC-free and latex-free urinary continence and urine drainage care products for the extended care and acute care markets. Our products are comprised of our base products, which include our male external catheters and standard silicone Foley catheters, and our advanced products, which include our intermittent catheters, our anti-infection Foley catheters and our *FemSoft Insert.* We market our products under our *Rochester Medical®* brand, and also supply our products to several large medical product companies for sale under brands owned by these companies, which are referred to as private label sales. The primary markets for our products are distributors, extended care facilities and individual hospitals and healthcare institutions. We sell our products both in the domestic market and internationally. International sales accounted for approximately 57% and 49% of total sales in 2007 and 2006 respectively.

Net sales for our fiscal year ended September 30, 2007 were $32.7 million, an increase of 50.8% from $21.7 million in the prior fiscal year. The increase in net sales was a result of an increase in both branded and private label sales. The increase in branded sales primarily was attributable to an increase in sales of advanced products and increased sales in the United Kingdom related to the asset acquisition we completed in June 2006. Private label sales of both base products and advanced products were up over last year.

Our five largest customers in fiscal 2007 represented approximately 40% of our total net sales. Because our larger customers typically purchase products in relatively large quantities at a time, our financial performance can fluctuate from quarter to quarter depending upon the timing of their purchases. We expect to continue to depend upon a relatively small number of customers for a significant percentage of our net sales.

A significant portion of our net sales to date have depended on our ability to provide products that meet the requirements of medical product companies that resell or distribute our products, and on the sales and marketing efforts of such entities. Arrangements with these entities are likely to continue to be a significant portion of our revenues in the future, while we continue to establish our own market presence under the *Rochester Medical* brand name.

Our manufacturing facilities, which we own, are located in Stewartville, Minnesota, and have been designed to accommodate the specialized requirements for the manufacture of medical devices, including FDA requirements for Quality System Regulation. A substantial portion of the expenses associated with our manufacturing facilities are fixed in nature (i.e. depreciation) and will reduce our operating margin until such time, if ever, as we are able to increase utilization of our capacity through increased sales of our new products.

Recent events that have contributed to the recent growth of our business include:

- On June 2, 2006, we, through our subsidiary Rochester Medical Limited, completed the acquisition of certain assets of Coloplast A/S ("Coloplast") and Mentor Medical Limited ("MML"). Through the acquisition, we acquired certain assets, including certain trademarks, related to sales of male external catheters, or MECs, in the United Kingdom. The assets also included MML's sales offices and warehouse facility in Lancing, England.
- We also entered into a separately negotiated Private Label Distribution Agreement with Coloplast under which we supply silicone MECs to Coloplast, which are sold under Coloplast's brands worldwide excepting the United Kingdom. The Private Label Distribution Agreement specifies annual minimum purchases of silicone MECs by Coloplast. Coloplast also supplies us with our requirement of latex MECs which we will sell in the United Kingdom under our newly acquired *Freedom®* and *Freedom Plus®* brands.
- On June 2, 2006, we separately completed the acquisition of certain assets owned and used by Mentor Corporation ("Mentor") in its silicone MEC business. We acquired certain equipment and other tangible

assets in Mentor's facility in Anoka, Minnesota, and purchased certain inventory, work-in-progress and raw materials for the production of silicone MECs; we also leased the Anoka facility from Mentor for six months following the closing of the transaction until we were able to transfer the assets to our Stewartville facilities. Upon the closing of the transactions, the existing Supply Agreement, Foley Catheter Sales and Distribution Agreement and MEC License and Sales Distribution Agreement (including, but not limited to the Patent License and Technology License thereunder) between us and Mentor were terminated, and Mentor conveyed to us all intellectual property exclusively related to the manufacturing and sale of silicone MECs at the Anoka facility.

- On November 6, 2006, we announced we had been awarded a national Group Purchasing Contract for urological products from Premier Purchasing Partners, L.P. ("Premier"). The agreement became effective March 1, 2007. Premier is one of the largest Group Purchasing Organizations in the United States with over $27 billion in contract purchases per year. Its members include more than 1,500 hospital facilities and hundreds of other care sites. The contract includes our Foley catheters (including our infection control catheters), MECs, intermittent catheters, and urethral inserts.

- On November 20, 2006, we announced that we had reached a settlement with Premier with respect to the lawsuit we initiated in February 2004 against certain GPOs and individual defendants alleging anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters. Under the settlement agreement, Premier paid us $8,825,000 (net $5,155,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit. On December 14, 2006, we announced we had reached a settlement with C.R. Bard, Inc., whereby C.R. Bard, Inc. paid us $49,000,000 (net $33,450,000 after payment of attorneys' fees and expenses), and was released from the lawsuit. On August 6, 2007, we announced that we had reached a settlement with Novation LLC with respect to the lawsuit. Under the settlement agreement, Novation is awarding us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced Infection Control catheters, and was dismissed from the lawsuit. The litigation continues against Tyco, which is scheduled for trial in February 2008. We cannot now estimate the prospects of a favorable outcome against Tyco.

- On December 11, 2006, we announced we had signed a new Private Label Agreement for supply of MECs to Hollister Incorporated for sale under the Hollister brand worldwide, excluding the United Kingdom, and also announced that we amended our 2003 OEM/Private Label Agreement. The two companies also agreed to terminate the Common Interest and Defense Agreement which we entered into in September 2004 for the defense of our Hydrophilic Intermittent catheter technology with respect to the patent infringement action in the United Kingdom between Coloplast A/S and Hollister. We have agreed with Hollister to release each other from any claims under the Common Interest and Defense Agreement. In particular, we will not be required to pay any additional legal fees under the terminated agreement.

- On August 6, 2007, we announced that Novation, LLC is awarding us an Innovative Technology Contract for its urological catheter products and related accessories, including our advanced infection control catheters. Novation provides contracting services to more than 2,500 members of VHA, Inc. and the University HealthSystem Consortium, or UHC, and nearly 9,000 members of Provista (formerly HPPI). The Innovative Technology Contract being awarded to us has a three year term from the effective date of September 1, 2007.

Our net income increased to $34,050,000 in fiscal 2007, which included approximately $31,000,000 from settlements of lawsuits net of taxes. We have generated only limited revenues to date and prior to fiscal 2003, experienced net losses since our inception. Net income for the fiscal years ended September 30, 2006, 2005, 2004 and 2003 was $1,959,000, $934,000, $747,000 and $330,000, respectively, while the net loss for the fiscal year ended September 30, 2002 was $1.4 million.

Application of Critical Accounting Policies

Management's Discussion and Analysis of Financial Condition and Results of Operations addresses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires that we 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, we evaluate these estimates and judgments. We base our estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

Inventories

Inventories are valued at the lower of cost, with cost being determined using a standard cost method, which approximates average cost, or the current estimated market value of the inventory. Our policy is to establish an excess and obsolete reserve for our products in excess of the expected demand for such products. At September 30, 2007, this reserve was $117,000, compared to $82,000 at September 30, 2006. If actual future collections or customer liquidity conditions differ from those projected by us, additional inventory valuation adjustments may be required. These valuation adjustments would be included in cost of goods sold.

Accounts Receivable

We maintain an allowance for doubtful accounts, which is calculated by a combination of specific account identification as well as percentages of past due balances. At September 30, 2007, this allowance was $58,000 compared to $56,000 at September 30, 2006. If actual future demand or market conditions differ from those projected by us, additional receivables valuation adjustments may be required. We perform periodic credit evaluations of our customers' financial condition. We require irrevocable letters of credit on sales to certain foreign customers. Receivables generally are due within 30 to 60 days.

Revenue Recognition

We recognize non-Group Purchase Organization related revenue from product sales upon shipment when title transfers to customers provided there are no remaining performance obligations required of the Company or any matters requiring customer acceptance. Revenue is recognized on Group Purchase Organization related sales upon delivery to the customer. Amounts received for upfront license fees under multiple-element supply and distribution arrangements are deferred and recognized over the period of supply, if such arrangements require our on-going services or performance.

Income Taxes

The carrying value of our net deferred tax assets assumes that we will be able to generate sufficient taxable income in the United States, based on estimates and assumptions. We record a valuation allowance to reduce the carrying value of our net deferred tax asset to the amount that is more likely than not to be realized. During 2005 management concluded that we had attained a sufficient level of sustained profitability to allow the valuation allowance to be reduced to reflect management's estimate of the amount of deferred tax assets that will be realized in the near term. Considering projected levels of future income as well as the nature of the net deferred tax assets, management reduced the valuation allowance by $454,000 during 2005 resulting in a corresponding income tax benefit in the statement of operations, and management further reduced the allowance by $777,000 in 2006 to reflect management's revised and increased estimates of future taxable income. During 2007, our earnings were sufficient to determine all deferred tax assets will be realized and the valuation allowance was therefore reduced to zero. We utilized our entire $21.0 million net operating loss in the current year which reduced the overall effective state and federal income tax rates. As a result, we recorded $8.4 million for income tax expense. On a quarterly basis, we evaluate the realizability of our deferred tax assets and assess the requirements for a valuation allowance.

Valuation of Goodwill and Other Intangibles

When we acquire a company, the purchase price is allocated, as applicable, between identifiable trademarks, other intangible assets, net tangible assets, and goodwill as required by U.S. generally accepted accounting principles . Determining the portion of the purchase price allocated to the trademarks and other intangible assets requires us to make significant estimates. The amount of the purchase price allocated to trademarks and other intangible assets is determined by estimating the future cash flows of each trademark or technology and discounting the net cash flows back to their present values. The discount rate used is determined at the time of acquisition in accordance with accepted valuation methods.

Goodwill represents the excess of the aggregate purchase price over the fair value of net assets of the acquired business. Goodwill is tested for impairment annually on the anniversary date of the acquisition, or more frequently if changes in circumstance or the occurrence of events suggest that the carrying amount may be impaired. We have determined the reporting unit continues to be at the enterprise level. In our judgment, the market capitalization of our company is the best indicator of the fair value of the reporting unit and have used the market capitalization of our company in our annual impairment test. Goodwill was $5.9 million and $5.5 million as of September 30, 2007 and 2006, respectively.

Other intangible assets consist primarily of purchased technology, patents and trademarks and are amortized using the straight-line method, as appropriate, over their estimated useful lives, ranging from 3 to 20 years. As of April 27, 2007, all of our intangible assets are definite-lived and amortized on a straight-line basis. We review these intangible assets for impairment annually or as changes in circumstance or the occurrence of events suggest the remaining value may not be recoverable. Other intangible assets, net of accumulated amortization, were $7.8 million and $8.3 million as of September 30, 2007 and 2006, respectively.

Long-Lived Assets

We follow Statement of Financial Accounting Standards ("SFAS") No. 144, "*Accounting for the Impairment of Disposal of Long-Lived Assets*." As such, we review our long-lived assets for impairment whenever events or changes in circumstances indicate that our carrying value of long-lived assets may not be recoverable. Long-lived assets are considered not recoverable when the carrying amount of a long-lived asset (asset group) exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset (asset group). If it is determined that a long-lived asset (asset group) is not recoverable, an impairment loss is recorded equal to the excess of the carrying amount of the long-lived asset (asset group) over the long-lived asset's (asset group's) fair value. Fair value is the amount at which the long-lived asset (asset group) could be bought or sold in a current transaction between a willing buyer and seller, other than in a forced or liquidation sale.

Stock-Based Compensation

Effective October 1, 2005, we adopted the provisions of, and account for stock-based compensation in accordance with SFAS No. 123 (Revised 2004), "*Share-Based Payment*" ("SFAS 123(R)"). Under the fair value recognition provisions of SFAS No. 123(R), we measure stock-based compensation cost at the grant date based on the fair value of the award and recognize the compensation expense over the requisite service period, which is generally the vesting period. We elected the modified-prospective method of adopting SFAS No. 123(R), under which prior periods are not retroactively revised. Estimated stock-based compensation expense for the non-vested portion of awards granted prior to the effective date is being recognized over the remaining service period using the compensation cost estimated for SFAS No. 123, "*Accounting for Stock-Based Compensation*" (SFAS No. 123), pro forma disclosures. Total stock-based compensation expense recognized during the fiscal year ended September 30, 2007 was $1.4 million after-tax ($2.1 million pre-tax). See Note 2 to our consolidated financial statements for further information regarding our stock-based compensation programs.

We use the Black-Scholes option pricing model to determine the fair value of stock options as of the grant date. The fair value of stock options under the Black-Scholes model requires management to make assumptions regarding projected employee stock option exercise behaviors, risk-free interest rate, volatility of our stock price and expected dividends.

We analyze historical employee stock option exercise and termination data to estimate the expected life assumption. We believe that historical data currently represents the best estimate of the expected life of a new employee option. We also stratify our employee population based upon distinctive exercise behavior patterns. The risk-free interest rate we use is based on the yield, on the grant date, of a zero-coupon U.S. Treasury bond whose maturity period equals or approximates the option's expected term. We calculate the expected volatility based solely on historical volatility which continues to be the most appropriate measure for us. The dividend yield rate used is zero as we have not nor expect to pay dividends. The amount of stock-based compensation expense we recognize during a period is based on the portion of the awards that are ultimately expected to vest. We estimate pre-vesting option forfeitures at the time of grant by analyzing historical data and revise those estimates in subsequent periods if actual forfeitures differ from those estimates.

If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the expense associated with new awards in future periods may differ significantly from what we have recorded in the current period related to historical awards and could materially affect our net earnings and diluted earnings per share of a future period. There were no modifications to any of our plans in 2007.

There is a risk that our estimates of the fair values of our stock-based awards on the grant dates as determined using the Black-Scholes model may bear little resemblance to the actual values realized upon the exercise or forfeiture of those stock-based awards in the future. Some employee stock options may expire without value, or only realize minimal intrinsic value, as compared to the fair values originally estimated on the grant date and recognized in our financial statements. Alternatively, some employee stock options may realize significantly more value than the fair values originally estimated on the grant date and recognized in our financial statements.

Results of Operations

The following table sets forth, for the periods indicated, certain items from our statements of operations expressed as a percentage of net sales:

	Fiscal Years Ended September 30,		
	2007	2006	2005
Total net sales	100%	100%	100%
Cost of sales	48	60	65
Gross margin	52	40	35
Operating expenses:			
Marketing and selling	20	14	15
Research and development	3	4	5
General and administrative	20	15	13
Total operating expenses	43	33	33
Income from operations	9	7	2
Other income	119	—	—
Interest income (expense), net	2	(1)	1
Net income before income taxes	130%	6%	3%

Our products are comprised of our base products, which include our male external catheters and standard silicone Foley catheters, and our advanced products, which include our intermittent catheters, our anti-infection Foley catheters and our *FemSoft Insert*. The following table sets forth, for the periods indicated, net sales information by product category (base products and advanced products), marketing method (private label and *Rochester Medical* branded sales) and distribution channel (domestic and international markets) (all dollar amounts below are in thousands):

	Fiscal Years Ended September 30,								
	2007			2006			2005		
	Domestic	International	Total	Domestic	International	Total	Domestic	International	Total
Private label sales:									
Base products	$ 7,635	$ 4,200	$11,835	$ 5,596	$ 4,406	$10,002	$4,100	$4,156	$ 8,256
Advanced products	1,042	550	1,592	646	100	746	250	139	389
Total private label sales	8,677	4,750	13,427	6,242	4,506	10,748	4,350	4,295	8,645
Branded sales:									
Base products	3,576	13,586	17,162	3,368	5,706	9,074	3,208	2,893	6,101
Advanced products	1,678	396	2,074	1,383	461	1,844	884	312	1,196
Total branded sales	5,254	13,982	19,236	4,751	6,167	10,918	4,092	3,205	7,297
Total net sales:	$13,931	$18,732	$32,663	$10,993	$10,673	$21,666	$8,442	$7,500	$15,942

Fiscal Year Ended September 30, 2007 Compared to Fiscal Year Ended September 30, 2006

Net Sales. Net sales increased 50.8% to $32.7 million in fiscal 2007 from $21.7 million in the prior fiscal year. The increase in net sales was a result of an increase in both branded and private label sales. The increase in branded sales primarily was attributable to increased sales of branded base products in the United Kingdom related to the asset acquisition. Domestic sales of branded products increased by 10% for fiscal 2007 compared to fiscal 2006. Our international branded sales increased 127% compared to fiscal 2006. Private label sales of both base products and advanced products were up over last year, primarily as a result of the new private label agreements entered into with Coloplast and Hollister in June and December 2006, respectively.

Gross Margin. Our gross margin as a percentage of net sales was 52% in fiscal 2007 compared to 40% in the prior fiscal year. Our increase in gross margin in fiscal 2007 was primarily due to increased sales volumes and increased sales of higher margin products.

Marketing and Selling. Marketing and selling expense primarily includes costs associated with base salary paid to sales and marketing personnel, sales commissions, and travel and advertising expense. Marketing and selling expense increased 108% in fiscal 2007 as compared to fiscal 2006, with marketing and selling expense of approximately $6.5 million in fiscal 2007 and $3.1 million in fiscal 2006. The increase in marketing and selling expense is primarily related to increased sales personnel and related expenses of $2.0 million incurred in the Company's U.K. operations, $1.0 million in increased staff in U.S. acute care marketing and $267,000 of increased stock-based compensation expense related to stock options in accordance with the reporting requirements of SFAS 123(R). Marketing and selling expense as a percentage of net sales for fiscal 2007 was 20% compared to 14% for fiscal 2006.

Research and Development. Research and development expense primarily includes internal labor costs, as well as expense associated with third-party vendors performing validation and investigative research regarding our products and development activities. Research and development expense increased 24% to $943,000 in fiscal 2007 from $760,000 in the prior fiscal year. The increase in research and development expense relates primarily to increased compensation expense of $101,000 and $70,000 of increased stock-based compensation expense related to stock options in accordance with the reporting requirements of SFAS 123(R). Research and development expense as a percentage of net sales for fiscal 2007 was 3% and fiscal 2006 was 4%.

General and Administrative. General and administrative expense primarily includes payroll expense related to our management and accounting, information technology and human resources staff, as well as fees and expenses of outside legal counsel, accounting advisors and auditors. General and administrative expense increased 102% to

$6.7 million in fiscal 2007 from $3.3 million in the prior fiscal year. The increase in general and administrative expense is primarily related to increased administrative costs of $1.2 million of increased stock-based compensation expense related to stock options in accordance with the reporting requirements of SFAS 123(R), $910,000 associated with our U.K. operations, $184,000 of compensation expense for bonus compensation under our annual incentive program, $363,000 of additional depreciation and amortization primarily related to our U.K. operations and $356,000 in expenses related to our preparation for compliance with Section 404 of the Sarbanes-Oxley Act. General and administrative expense as a percentage of net sales for fiscal 2007 and fiscal 2006 was 21% and 15%, respectively.

Interest Income. Interest income increased 600% to $1.5 million in fiscal 2007 from $220,000 in the prior fiscal year. The increase reflects significantly higher cash positions as a result of the lawsuit settlements with Premier and C.R. Bard in the first quarter, and an overall higher interest rate on investments.

Other Income. Other income of approximately $39 million is primarily the result of lawsuit settlements with Premier and C.R. Bard.

Interest Expense. Interest expense increased 128% to $513,000 in fiscal 2007 from $225,000 in fiscal 2006. The increase in interest expense reflects increases in debt used to partially finance our asset acquisitions in June 2006 from Mentor and Coloplast.

Income Taxes. We had a history of pre-tax losses and until fiscal 2003 had not generated taxable income. While we had pre-tax income in fiscal 2006, 2005, 2004 and 2003, we utilized a portion of our net operating loss carryforward and therefore, no federal income taxes are due for fiscal 2006, 2005, 2004 or fiscal 2003. During fiscal 2007, our taxable earnings were sufficient to fully utilize the net operating loss carryforward of $21.0 million. Income taxes payable are a result of taxable income remaining after net operating loss utilization.

We established a deferred tax asset of $454,000 in fiscal 2005. As a result of the asset acquisition discussed above, management further reduced the valuation allowance by approximately $777,000 to reflect management's revised and increased estimates of future taxable income. Since our current year taxable earnings were sufficient to determine it more likely than not that all deferred tax assets will be realized, the valuation allowance was reduced to zero.

As of September 30, 2007, we have no federal net operating loss carryforwards available to offset future taxable income, since our earnings were sufficient to fully utilize the net operating loss carryforward of $21.0 million during fiscal 2007.

Net Income. Our net income increased to $34,050,000 in fiscal 2007. Lawsuit settlements along with increased sales and gross margin were primarily responsible.

Fiscal Year Ended September 30, 2006 Compared to Fiscal Year Ended September 30, 2005

Net Sales. Net sales increased 35.9% to $21.7 million in fiscal 2006 from $15.9 million in the prior fiscal year. The increase in net sales was a result of an increase in branded and private label sales. The increase in branded sales primarily was attributable to increased sales of advanced products and increased sales in the United Kingdom related to the asset acquisition. Private label sales of both base products and advanced products were up over the prior year.

Gross Margin. Our gross margin as a percentage of net sales was 40% in fiscal 2006 compared to 35% in the prior fiscal year. Our increase in gross margin in fiscal 2006 was primarily due to increased sales.

Marketing and Selling. Marketing and selling expense primarily includes costs associated with base salary paid to sales and marketing personnel, sales commissions, and travel and advertising expense. Marketing and selling expense increased 30% in fiscal 2006 as compared to fiscal 2005, with marketing and selling expense of approximately $3.1 million in fiscal 2006 and $2.4 million in fiscal 2005. The increase in marketing and selling expense is primarily related to increased sales personnel and related expenses of $654,000 incurred through the addition of our new U.K. operations, and $132,000 of increased stock-based compensation expense related to stock options in accordance with the new reporting requirements of SFAS 123(R). Marketing and selling expense as a percentage of net sales for fiscal 2006 was 14% compared to 15% for fiscal 2005.

Research and Development. Research and development expense primarily includes internal labor costs, as well as expense associated with third-party vendors performing validation and investigative research regarding our products and development activities. Research and development expense increased 4% to $760,000 in fiscal 2006 from $730,000 million in the prior fiscal year. The increase in research and development expense relates primarily to increased compensation expense of $63,000 and $60,000 of increased stock-based compensation expense related to stock options in accordance with the new reporting requirements of SFAS 123(R), offset by a decrease in product development costs. Research and development expense as a percentage of net sales for fiscal 2006 was 4% and fiscal 2005 was 5%.

General and Administrative. General and administrative expense primarily includes payroll expense related to our management and accounting, information technology and human resources staff, as well as fees and expenses of outside legal counsel, accounting advisors and auditors. General and administrative expense increased 57% to $3.3 million in fiscal 2006 from $2.1 million in the prior fiscal year. The increase in general and administrative expense is primarily related to increased administrative costs of $289,000 associated with the addition of our U.K. operations, $197,000 of compensation expense for bonus compensation under our annual incentive program, $239,000 of depreciation and amortization related to the U.K. addition, $50,000 in professional fees and $408,000 of increased stock-based compensation expense related to stock options in accordance with the new reporting requirements of SFAS 123(R). General and administrative expense as a percentage of net sales for fiscal 2006 and fiscal 2005 was 15% and 13%, respectively.

Interest Income. Interest income increased 59% to $220,000 in fiscal 2006 from $139,000 in the prior fiscal year offset by a loss on sale of investments of $104,000. The increase reflects significantly higher cash positions and an overall higher interest rate on investments during the first eight months of the year reduced by the sale of investments used to fund our purchase of certain assets from Mentor and Coloplast in June 2006 transactions.

Interest Expense. Interest expense increased to $225,000 in fiscal 2006 from $15,000 in fiscal 2005. The increase in interest expense reflects increases in debt used to partially finance our asset acquisitions discussed above.

Income Taxes. We had a history of pre-tax losses and until fiscal 2003 had not generated taxable income. While we had pre-tax income in fiscal 2006, 2005, 2004 and 2003, we utilized a portion of our net operating loss carryforward and therefore, no federal income taxes are due for fiscal 2006, 2005, 2004 or fiscal 2003. Income taxes payable are a result of taxable income in the United Kingdom which reduced our income tax benefit.

We established a deferred tax asset of $454,000 in fiscal 2005. As a result of the asset acquisition discussed above, management further reduced the valuation allowance by approximately $777,000 to reflect management's revised and increased estimates of future taxable income. Accordingly, the net deferred income tax asset as of September 30, 2006, represented an estimate of the tax benefit to be realized based on projected taxable income over the next three years with a corresponding reduction in our deferred tax asset related to the tax loss carryforward. We established a valuation allowance against the remaining amount of our deferred tax asset.

As of September 30, 2006, we had $21.6 million of federal net operating loss carryforwards available to offset future taxable income.

Net Income. Our net income increased 110% to $1,959,000 in fiscal 2006. Increased sales and gross margin, along with the booking of our deferred tax asset, was partially offset by higher operating expenses.

Liquidity and Capital Resources

We have historically financed our operations primarily through public offerings and private placements of our equity securities, and have raised approximately $40.7 million in net proceeds since our inception.

Our cash, cash equivalents and marketable securities were $37.1 million at September 30, 2007 compared with $2.9 million at September 30, 2006. The increase in cash primarily resulted from the lawsuit settlements with both Premier and C.R. Bard and cash provided by stock option exercises and operations offset by cash used for capital expenditures and debt repayments.

We generated a net $35.5 million of cash in operating activities during the year compared with $2.8 million for the same period last year, primarily as a result of the lawsuit settlements. Cash flow provided by operating activities in 2007 was comprised of net income of $34 million reduced by an increase in net working capital components and increased by net non-cash charges of $3.2 million, primarily depreciation and amortization of $1.9 million and stock-based compensation of $2.1 million. Income tax payable increased $501,000 for the fiscal year related to taxes payable in the U.S. Significant working capital changes are as follows:

- a $877,000 increase in accounts receivable reflecting increasing sales activity over prior year.
- a $2,967,000 increase in inventory as we increased our finished goods and work-in-process inventory to support the increase in sales volume.
- a $501,000 increase in taxes payable due to us generating taxable income in excess of our previous net operating losses.

In fiscal 2002, we entered into an agreement with Coloplast granting Coloplast exclusive marketing and distribution rights with respect to our *Release-NF* Foley catheters in certain geographic areas. Coloplast paid us $1,000,000 for these exclusive rights. This agreement was terminated by mutual consent in fiscal 2007. In addition, during the fiscal quarter ended September 30, 2003, we entered into an agreement granting Hollister Inc. exclusive marketing and distribution rights in certain geographic areas with respect to our hydrophilic intermittent catheters in exchange for a cash payment of $200,000. This agreement was amended in December 2006, and continues through December 31, 2008, although on a non-exclusive basis.

During fiscal 2007, our working capital position, excluding cash and marketable securities, increased by $4.4 million. Accounts receivable balances increased 40% or $877,000 during the fiscal year primarily due to increased sales. Inventories as of September 30, 2007 increased $3.0 million or 63% over fiscal 2006 as we carried more inventory in anticipation of increased sales. Other current assets were relatively flat with fiscal 2006. Changes in other asset and liability balances related to timing differences.

Investing activities, primarily capital expenditures and the purchase of marketable securities, used net cash of $33.1 million in fiscal 2007.

On June 2, 2006, in conjunction with the financing of the transactions between us, Mentor and Coloplast, we entered into a $7,000,000 credit facility with U.S. Bank National Association. The credit facility replaced the prior $1,000,000 revolving line of credit with U.S. Bank that expired on March 31, 2006. The credit facility consists of a $5,000,000 term loan payable in five years and accruing interest at a rate equal to 6.83%, and a revolving line of credit of up to $2,000,000, maturing annually beginning March 31, 2007, with interest payable monthly at a floating rate based on the quoted one-month LIBOR rate plus 1.60%. As of September 30, 2007, we had no borrowings under the revolving line of credit. Our obligations are secured by our assets, including accounts, general intangibles, inventory, and equipment. The term loan agreement and revolving credit agreement require us to comply with certain financial covenants beginning with the first quarter of fiscal 2007, including a fixed charge coverage ratio and minimum working capital of $8 million, and restrict certain additional indebtedness and liens. As of September 30, 2007, we were in compliance with the financial covenants.

In June 2006, in conjunction with the asset purchase agreement with Coloplast, we entered into an unsecured loan note deed with Coloplast with an outstanding principal amount of $5,340,000. The promissory note is non-interest bearing payable and due in five equal installments of $1,068,000 payable annually on June 2. We have discounted the $5,340,000 note at 6.90% and reflect a $4,010,000 liability on our balance sheet as of September 30, 2007.

On November 20, 2006, we announced that we had reached a settlement with Premier with respect to the lawsuit we initiated in February 2004 against certain Group Purchase Organizations and individual defendants alleging anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters. Under the settlement agreement, Premier paid us $8,825,000 (net $5,155,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit. On December 14, 2006, we announced we had reached a settlement with C.R. Bard, Inc., whereby C.R. Bard, Inc. paid us $49,000,000 (net $33,450,000 after payment of attorneys' fees and expenses) and was released from the lawsuit.

We currently believe that our existing resources and anticipated cash flows from operations will be sufficient to satisfy our capital needs for the foreseeable future. However, our actual liquidity and capital requirements will depend upon numerous factors, including the costs, method and timing of expansion of sales and marketing activities; the amount of revenues from sales of our existing and new products; changes in, termination of, and the success of, existing and new distribution arrangements; the cost of maintaining, enforcing and defending patents and other intellectual property rights; competing technological and market developments; developments related to regulatory and third party reimbursement matters; the cost and progress of our research and development efforts; opportunities for growth through acquisition, joint venture or other business combinations, if any; and other factors. In the event that additional financing is needed, we may seek to raise additional funds through public or private financing, collaborative relationships or other arrangements. Any additional equity financing may be dilutive to shareholders, and debt financing, if available, may involve significant restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish our rights to certain of our technologies, products or marketing territories. Failure to raise capital when needed could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that such financing, if required, will be available on terms satisfactory to us, if at all.

Disclosures about Contractual Obligations and Commercial Commitments

The following table summarizes our contractual commitments and commercial obligations that affect our financial condition and liquidity position as of September 30, 2007:

	Payments Due by Period				
Contractual Obligations	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Long Term Debt, including interest . .	$8,370,547	$2,255,960	$6,114,587	$—	$—
Purchase Obligations (general operating)	413,164	413,164	—	—	—
Total Contractual Cash Obligations	$8,783,711	$2,669,124	$6,114,587	$—	$—

Off-Balance Sheet Arrangements

As of September 30, 2007, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

New Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, as amended, *Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement 109* ("FIN 48"), which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in our financial statements only if the position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of fiscal 2008, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 establishes a single authoritative definition of fair value, establishes a framework for measuring fair value, and expands disclosure requirements pertaining to fair value measurements. The original pronouncement of SFAS 157 was effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. On a recent meeting, the FASB agreed to defer the effective date of this pronouncement and has agreed to issue additional guidance on specific related topics. We will continue to evaluate the impact that this guidance, as amended, will have on our results of operations and financial position. Based on our understanding of the original pronouncement, the impact would have been immaterial.

In September 2006, the SEC staff issued Staff Accounting Bulletin 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"). SAB 108 requires that public companies utilize a "dual-approach" to assessing the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet focused assessment. We adopted SAB 108 in fiscal 2007 without any impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We are currently assessing the impact of SFAS 159 on our consolidated financial position and results of operations.

In June 2006, the FASB ratified Emerging Issues Task Force ("EITF") Issue No. 06-03, "*How Taxes Collected form Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation).*" EITF 06-03 requires companies to disclose the amount of taxes assessed by a governmental authority and recorded on a gross basis in interim and annual financial statements. We will be required to adopt EITF 06-03 as of October 1, 2007. We do not expect that the adoption of EITF 06-03 will have a material impact on our results of operations or cash flows.

Cautionary Statement Regarding Forward Looking Information

Statements other than historical information contained herein constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may be identified by the use of terminology such as "believe," "may," "will," "expect," "anticipate," "predict," "intend," "designed," "estimate," "should" or "continue" or the negatives thereof or other variations thereon or comparable terminology. Such forward-looking statements involve known or unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements, or industry results, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, the following:

- the uncertainty of market acceptance of new product introductions;
- the uncertainty of gaining new strategic relationships;
- the uncertainty of timing of revenues from private label sales (particularly with respect to international customers);
- the uncertainty of successfully integrating and growing our new UK operations and the risks associated with operating an international business;
- FDA and other regulatory review and response times;
- the securing of Group Purchasing Organization contract participation;
- the uncertainty of gaining significant sales from secured GPO contracts;
- and other risk factors listed from time to time in our SEC reports, including, without limitation, the section entitled "Risk Factors" in Item 1A of this Form 10-K.

Management's Report on Internal Control over Financial Reporting

Management of the company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally

accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the company's internal control over financial reporting as of September 30, 2007. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework.

Based on our assessment and those criteria, management believes that the company maintained effective internal control over financial reporting as of September 30, 2007.

Our independent auditors have audited our consolidated financial statements and the effectiveness of our internal control over financial reporting as of September 30, 2007, as stated in their reports on pages 34 and 35. .

ITEM 7A. Quantitative and Qualitative Disclosures about Market Risk.

Our primary financial instrument market risk results from fluctuations in interest rates. Our cash is invested in bank deposits and money market funds denominated in United States dollars and British pounds. The carrying value of these cash equivalents approximates fair market value. Our investments in marketable securities are subject to interest rate risk and the value thereof could be adversely affected due to movements in interest rates. Our revolving line of credit bears interest at a floating rate based on the quoted one-month LIBOR rate plus 1.60%. As of September 30, 2007, we had no borrowings under the revolving line of credit.

In future periods, we believe a greater portion of our revenues could be denominated in currencies other than the U.S. dollar, thereby increasing our exposure to exchange rate gains and losses on non-United States currency transactions. Sales through our subsidiary, Rochester Medical, Ltd., are denominated in British pounds, and fluctuations in the rate of exchange between the U.S. dollar and the British pound could adversely affect our financial results.

Otherwise, we do not believe our operations are currently subject to significant market risks for interest rates, foreign currency exchange rates, commodity prices or other relevant market price risks of a material nature. We do not currently use derivative financial instruments to manage interest rate risk or enter into forward exchange contracts to hedge exposure to foreign currencies, or any other derivative financial instruments for trading or speculative purposes. In the future, if we believe an increase in our currency exposure merits further review, we may consider entering into transactions to mitigate that risk.

ITEM 8. Financial Statements and Supplementary Data

Rochester Medical Corporation
Consolidated Financial Statements

Years Ended September 30, 2007, 2006 and 2005

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
of Rochester Medical Corporation

We have audited the consolidated balance sheets of Rochester Medical Corporation and subsidiary as of September 30, 2007 and 2006, and the related consolidated statements of operations, shareholders' equity and comprehensive income, and cash flows for each of the three years in the period ended September 30, 2007. Our audits also included the financial statement schedule of Rochester Medical Corporation listed in Item 15(a). These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Rochester Medical Corporation and subsidiary as of September 30, 2007 and 2006, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2007, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Rochester Medical Corporation's and subsidiary's internal control over financial reporting as of September 30, 2007, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated December 3, 2007 expressed an unqualified opinion on management's assessment of the effectiveness of Rochester Medical Corporation's and subsidiary's internal control over financial reporting and an unqualified opinion on the effectiveness of Rochester Medical Corporation's and subsidiary's internal control over financial reporting.

/s/ McGladrey & Pullen LLP

Minneapolis, Minnesota
December 3, 2007

To the Board of Directors and Shareholders
of Rochester Medical Corporation

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Rochester Medical Corporation and subsidiary maintained effective internal control over financial reporting as of September 30, 2007, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Rochester Medical Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Rochester Medical Corporation and subsidiary maintained effective internal control over financial reporting as of September 30, 2007, is fairly stated, in all material respects, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also in our opinion, Rochester Medical Corporation and subsidiary maintained, in all material respects, effective internal control over financial reporting as of September 30, 2007, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Rochester Medical Corporation and subsidiary as of September 30, 2007 and 2006, and the related consolidated statements of operations, shareholders' equity and comprehensive income, and cash flows of Rochester Medical Corporation and subsidiary for each of the three years in the period ended September 30, 2007 and our report dated December 3, 2007 expressed an unqualified opinion.

/s/ McGladrey & Pullen LLP

Minneapolis, Minnesota
December 3, 2007

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS

	September 30, 2007	September 30, 2006
Assets:		
Current assets:		
Cash and cash equivalents	$ 6,671,356	$ 2,906,698
Marketable securities	30,465,244	—
Accounts receivable, less allowance for doubtful accounts ($57,913 — 2007; $55,540 — 2006)	5,527,518	4,494,094
Inventories, net	7,698,889	4,642,578
Prepaid expenses and other current assets	6,480	410,267
Deferred income tax asset	876,032	53,000
	51,245,519	12,506,637
Property, plant and equipment:		
Land	365,952	365,951
Buildings	7,400,706	7,210,156
Equipment and fixtures	14,622,361	12,208,194
	22,389,019	19,784,301
Less accumulated depreciation	(12,709,984)	(11,545,055)
Total property, plant and equipment	9,679,035	8,239,246
Deferred income tax asset	571,721	1,178,000
Goodwill	5,920,255	5,487,141
Finite life intangibles, less accumulated amortization ($886,008 — 2007; $217,843 — 2006)	7,821,562	8,270,157
Patents, less accumulated amortization ($1,090,178 — 2007; $1,026,564 — 2006)	257,353	271,171
Total assets	$ 75,495,445	$ 35,952,352
Liabilities and Shareholders' Equity:		
Current liabilities:		
Accounts payable	$ 1,091,874	$ 1,278,441
Accrued compensation	1,109,533	756,834
Accrued expenses	869,404	970,101
Deferred revenue	—	114,287
Current maturities of debt	1,849,463	1,681,361
Current maturities of capital leases	—	42,084
Total current liabilities	4,920,274	4,843,108
Long-term liabilities:		
Deferred revenue	—	449,999
Long-term debt, less current maturities	6,066,246	7,540,737
Capital leases, less current maturities	—	21,946
Total long-term liabilities	6,066,246	8,012,682
Shareholders' equity:		
Common Stock, no par value:		
Authorized Shares — 40,000,000; Issued and outstanding shares: (11,690,886 — 2007; 11,086,560 — 2006)	50,150,739	43,128,727
Retained earnings (Accumulated deficit)	13,964,438	(20,085,742)
Accumulated other comprehensive income	393,748	53,577
Total shareholders' equity	64,508,925	23,096,562
Total liabilities and shareholders' equity	$ 75,495,445	$ 35,952,352

See accompanying notes.

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Fiscal Years Ended September 30,		
	2007	2006	2005
Net sales	$32,663,087	$21,665,837	$15,941,649
Cost of sales	15,619,178	13,057,090	10,330,113
Gross profit	17,043,909	8,608,747	5,611,536
Operating expenses:			
Marketing and selling	6,490,497	3,109,207	2,397,816
Research and development	943,225	759,639	730,105
General and administrative	6,742,665	3,344,662	2,126,813
Total operating expenses	14,176,387	7,213,508	5,254,734
Income from operations	2,867,522	1,395,239	356,802
Other income (expense):			
Interest income	1,288,603	116,341	138,692
Other income	38,855,000	—	—
Interest (expense)	(513,296)	(224,848)	(15,067)
	39,630,307	(108,507)	123,625
Net income before income taxes	42,497,829	1,286,732	480,427
Income tax benefit (expense)	(8,447,649)	672,176	454,000
Net income	$34,050,180	$ 1,958,908	$ 934,427
Net income per common share — basic	$ 2.97	$ .18	$ .09
Net income per common share — diluted	$ 2.77	$ .17	$ .08
Weighted average number of common shares outstanding — basic	11,449,646	11,068,102	10,932,246
Weighted average number of common shares outstanding — diluted	12,272,172	11,665,992	11,429,230

See accompanying notes.

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENT OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE INCOME

	Common Stock		Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income	Total
	Shares	Amount			
Balance at September 30, 2004	10,882,262	$41,940,700	$(22,979,077)	$ (73,874)	$18,887,749
Net income for the year	—	—	934,427	—	934,427
Unrealized loss on available-for-sale securities	—	—	—	(1,200)	(1,200)
Subtotal-comprehensive income	—	—	—	—	933,227
Stock option exercise	164,738	467,212	—	—	467,212
Balance at September 30, 2005	11,047,000	42,407,912	(22,044,650)	(75,074)	20,288,188
Net income for the year	—	—	1,958,908	—	1,958,908
Foreign currency translation adjustment	—	—	—	53,577	53,577
Unrealized loss on available-for-sale securities	—	—	—	75,074	75,074
Subtotal-comprehensive income	—	—	—	—	2,087,559
Stock option compensation	—	599,527	—	—	599,527
Stock option exercise	39,560	121,288	—	—	121,288
Balance at September 30, 2006	11,086,560	43,128,727	(20,085,742)	53,577	23,096,562
Net income for the year	—	—	34,050,180	—	34,050,180
Foreign currency translation adjustment	—	—	—	443,534	443,534
Unrealized loss on available-for-sale securities	—	—	—	(103,363)	(103,363)
Subtotal-comprehensive income	—	—	—	—	34,390,351
Federal tax benefit of stock options exercised	—	2,325,866	—	—	2,325,866
Stock option compensation	—	2,117,011	—	—	2,117,011
Stock option exercise	604,326	2,579,135	—	—	2,579,135
Balance at September 30, 2007	11,690,886	$50,150,739	$ 13,964,438	$ 393,748	$64,508,925

See accompanying notes.

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Fiscal Years Ended September 30,		
	2007	2006	2005
Operating Activities:			
Net income	$ 34,050,180	$ 1,958,908	$ 934,427
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	1,161,291	962,698	1,208,946
Amortization	724,067	279,394	58,315
Stock based compensation	2,117,011	599,527	—
Deferred revenue	(564,286)	(157,142)	(157,142)
Deferred income taxes	(203,070)	(776,999)	(454,000)
Federal tax benefit of stock options exercised	2,325,866	—	—
Changes in operating assets and liabilities, net of the effects of business acquisitions:			
Accounts receivable	(877,450)	(1,267,082)	(573,635)
Inventories	(2,966,577)	(693,206)	9,071
Other current assets	(240,402)	(59,240)	(77,799)
Accounts payable	(197,366)	995,117	(495,434)
Income tax payable	500,688	—	—
Other current liabilities	(308,524)	982,675	149,112
Net cash provided by operating activities	35,521,428	2,824,649	601,860
Investing Activities:			
Capital expenditures	(2,482,625)	(354,182)	(327,822)
Business acquisition	60,579	(10,857,505)	—
Patents	(49,795)	(47,529)	(124,213)
Purchase of marketable securities	(36,557,555)	—	(1,133,075)
Sales and maturities of marketable securities	5,975,000	5,361,625	1,097,084
Net cash provided by investing activities	(33,054,396)	(5,897,591)	(488,026)
Financing Activities:			
Payments on capital leases	(64,030)	(39,785)	(37,611)
Proceeds from long-term financing	—	5,000,000	—
Payments on long-term financing	(1,744,919)	(250,000)	(34,000)
Sale of common stock upon exercise of options	2,579,135	121,288	467,212
Net cash provided by financing activities	770,186	4,831,503	395,601
Effect of exchange rate on cash	527,440	18,261	—
Increase in cash and cash equivalents	3,764,658	1,776,822	509,435
Cash and cash equivalents at beginning of year	2,906,698	1,129,876	620,441
Cash and cash equivalents at end of year	$ 6,671,356	$ 2,906,698	$ 1,129,876
Supplemental Cash Flow Information:			
Interest Paid	$ 604,635	$ 94,650	$ 15,665
Cash paid for income taxes	5.750,000	—	—
Supplemental disclosure of non-cash financing activities:			
Debt used to finance asset acquisition	$ —	$ 4,409,099	$ —

See accompanying notes.

1. Business Activity

Rochester Medical Corporation (the "Company") develops, manufactures and markets a broad line of innovative, technologically enhanced urinary continence and urine drainage care products for the home care and acute/extended care markets. The Company currently manufactures and markets standard continence care products, including male external catheters, Foley catheters and intermittent catheters and innovative and technologically advanced products such as its *FemSoft Insert*, *Release-NF* catheter and antibacterial and hydrophilic intermittent catheters. The Company markets its products under its Rochester Medical brand, and also supplies its products to several large medical product companies for sale under brands owned by these companies, which are referred to as private label sales. The accompanying financial statements include the accounts of Rochester Medical Corporation and its wholly owned subsidiary Rochester Medical Ltd. all of which are herein referred to as "the Company".

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All material intercompany accounts and transactions are eliminated in consolidation.

Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less when purchased to be cash equivalents. The Company maintains its cash in bank deposit accounts which, at times, may exceed the insurance limits of the Federal Deposit Insurance Corporation. The Company has not experienced any losses in such accounts.

Marketable Securities

Marketable securities are classified as available for sale and are carried at fair value, with unrealized gains or losses included as a separate component of shareholders' equity. At September 30, 2006, the Company did not own any marketable securities. At September 30, 2007 and 2005, the Company owned mainly municipal bonds. The cost and fair value of available-for-sale securities were as follows:

	Cost	Unrealized Loss	Fair Value	Proceeds From Sales	Realized Loss
September 30, 2007	$30,582,556	$(117,312)	$30,465,244	$5,975,000	—
September 30, 2006	—	—	—	$5,361,625	$(103,531)
September 30, 2005	$ 5,361,627	$ (75,074)	$ 5,286,553	$1,097,084	—

As of September 30, 2007, the Company has $30.5 million in high quality, investment grade debt securities, but is currently reporting an unrealized loss of $117,000. The Company considers these unrealized losses temporary as it has the intent and ability to hold these investments long enough to avoid realizing any significant losses.

Losses recognized are recorded in *interest expense* in the consolidated statements of operations. Gains and losses from the sale of investments are calculated based on the specific identification method.

Fair Value of Financial Instruments

The carrying amounts of all financial instruments, including cash, accounts receivable, amounts payable and accrued expenses approximate their fair values because of the short maturity of these instruments. The carrying

amounts of the Company's long-term debt approximates fair value based on current rates offered to the Company for debt of the same remaining maturities.

Concentration of Credit

The Company manufactures and sells its products to a full range of companies in the medical industry on a worldwide basis. There is a concentration of sales to larger medical wholesalers and distributors. The Company recognizes non-Group Purchase Organization related revenue from product sales upon shipment when title transfers to customers. Revenue is recognized on Group Purchase Organization related sales upon delivery to the customer. The Company performs periodic credit evaluations of its customers' financial condition. The Company requires irrevocable letters of credit on sales to certain foreign customers. Receivables generally are due within 30 to 60 days.

Accounts Receivable

The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables. The Company maintains an allowance for doubtful accounts for potential credit losses. Uncollectible accounts are written-off against the allowance when it is deemed that a customer account is uncollectible.

Inventories

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost or market. Cost is determined using a standard cost method, which approximates average cost.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation is based on estimated useful lives of 4-10 years for equipment and fixtures and 25-35 years for buildings computed using the straight-line method. Additions and improvements that extend the lives of the assets are capitalized while expenditures for repairs and maintenance are expensed as incurred.

Finite Life Intangible Assets

Finite life intangible assets consist primarily of purchased trademarks, a supply agreement, and customer relationships and are amortized using the straight-line method, as appropriate, over their estimated useful lives, ranging from 5 to 20 years. The Company reviews these intangible assets for impairment annually or as changes in circumstance or the occurrence of events suggest the remaining value may not be recoverable. No impairment loss was recognized in the fiscal years ended September 30, 2007 and 2006.

Foreign Currency Translation

The financial statements of the Company's non-U.S. subsidiary are translated into U.S. dollars in accordance with SFAS No. 52, "*Foreign Currency Translation*." The assets and liabilities of certain non-U.S. subsidiaries whose functional currencies are other than the U.S. dollar are translated at current rates of exchange. Revenue and expense items are translated at the average exchange rates. The resulting translation adjustments are recorded directly into accumulated other comprehensive income (loss).

Goodwill and Other Intangible Assets

The Company records as goodwill the excess of purchase price over the fair value of the identifiable net assets acquired as prescribed by Statement of Financial Accounting Standards ("SFAS") No. 142, "*Goodwill and Other Intangible Assets*" Under this standard, goodwill and intangibles with indefinite useful lives are not amortized. This standard also requires, at a minimum, an annual assessment of the carrying value of goodwill and other intangibles

with indefinite useful lives. If the carrying value of goodwill or an intangible asset exceeds its fair value, an impairment loss shall be recognized. No impairment loss was recognized in the fiscal years ended September 30, 2007 and 2006.

Long-Lived Assets

The Company reviews its long-lived assets for impairment as prescribed by SFAS No. 144, "*Accounting for the Impairment or Disposal of Long-Lived Assets*" whenever events or changes in circumstances indicate that its carrying value of long-lived may not be recoverable. Long-lived assets are considered not recoverable when the carrying amount of a long-lived asset (asset group) exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset (asset group). If it is determined that a long-lived asset (asset group) is not recoverable, an impairment loss is recorded equal to the excess of the carrying amount of the long-lived asset (asset group) over the long-lived asset's (asset group's) fair value. Fair value is the amount at which the long-lived asset (asset group) could be bought or sold in a current transaction between a willing buyer and seller, other than in a forced or liquidation sale. No impairment loss was recognized in the fiscal years ended September 30, 2007 and 2006.

Patents

Capitalized costs include costs incurred in connection with making patent applications for the Company's products and are amortized on a straight-line basis over eight years. The Company periodically reviews its patents for impairment of value. Any adjustment from the analysis is charged to operations.

Research and Development Costs

Research and development costs are charged to operations as incurred. Research and development costs include clinical testing costs, certain salary and related expenses, other labor costs, materials and an allocation of certain overhead expenses.

Revenue Recognition

The Company recognizes non-Group Purchase Organization related revenue from product sales upon shipment when title transfers to customers provided there are no remaining performance obligations required of the Company or any matters requiring customer acceptance. Revenue is recognized on Group Purchase Organization related sales upon delivery to the customer. Amounts received for upfront license fees under multiple-element supply and distribution arrangements are deferred and recognized over the period of supply, if such arrangements require the Company's on-going services or performance.

During the year ended September 30, 2007, the Company recognized $525,000 of deferred revenue related to a 10 year distribution agreement with Coloplast. As part of the original agreement, Coloplast paid the Company $1,000,000 for the exclusive right to market and sell the Release NF foley catheter in the U.K. for a period of 10 years. During the year, both companies mutually agreed to terminate the contract thus accelerating the recognition of the remaining deferred revenue of the Company.

Income Taxes

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between financial reporting and tax bases of assets and liabilities. The Company records a valuation allowance to reduce the carrying value of its net deferred tax assets to the amount that is more likely than not to be realized. During 2007, the Company's earnings were sufficient to determine it is more likely than not that all deferred tax assets will be realized and the valuation allowance was therefore reduced to zero.

Advertising Costs

The Company incurred advertising expenses of $397,000, $333,000 and $142,000 for the years ended September 30, 2007, 2006 and 2005, respectively. All advertising costs are charged to operations as incurred.

Stock-Based Compensation

Effective October 1, 2005, the Company adopted SFAS No. 123 (Revised 2004), "*Share-Based Payment*" ("SFAS 123(R)") which requires all share-based payments, including grants of stock options, to be recognized in the statement of operations as an operating expense based on their fair values over the requisite service period. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25 "*Accounting for Stock Issued to Employees*" for periods beginning in fiscal 2006. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ("SAB 107") relating to SFAS 123(R). The Company has applied the provisions of SAB 107 in its adoption of SFAS 123(R). The Company elected to utilize the modified-prospective transition method as permitted by SFAS 123(R). Under this transition method, the Company's financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R). Stock-based compensation expense for the year ended September 30, 2007 includes: (a) compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of, October 1, 2005, based on grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, "*Accounting for Stock-Based Compensation*;" and (b) compensation expense for all stock-based compensation awards granted subsequent to October 1, 2005, based on grant-date fair value estimated in accordance with the provisions of SFAS 123(R) recognized utilizing the accelerated expense attribution method for awards with graded vesting. The Company recorded approximately $2,100,000 and $600,000 ($1,365,000 and $390,000 net of tax) of related stock-based compensation expense for the year ended September 30, 2007 and 2006 respectively.

Pro forma information regarding net income (loss) and income (loss) per share is required by SFAS No. 123, and has been determined as if the Company had accounted for its employee stock options under the fair value method of SFAS No. 123. The fair value of these options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions for fiscal 2005: risk-free interest rate of 3.68%; volatility factor of the expected market price of the Company's common stock of .5458; a weighted average expected life of the option of 6.4 years; and an expected dividend yield of 0%.

The following table illustrates the effect on net earnings and net earnings per share for fiscal year 2005 if the Company had applied the fair value recognition provisions of SFAS No. 123 to its stock-based employee compensation:

	September 30, 2005
Net income, as reported	$ 934,427
Deduct: total stock-based employee compensation expense under fair value method for all awards	(439,130)
Pro forma net income	$ 495,297
Net Income per common share:	
Basic — as reported	$ .09
Diluted — as reported	$ .08
Basic — pro forma	$ .05
Diluted — pro forma	$ .04

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant items subject to estimates and assumptions include the valuation allowances for inventories, fair value assumptions related to investments and deferred income tax assets. Actual results could differ from those estimates.

Net Income Per Share

Net income per common share is calculated in accordance with Financial Accounting Standards Board Statement No. 128, "*Earnings Per Share.*" The Company's basic net income per common share is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted net income per common share is computed by dividing net income by the weighted average number of common shares outstanding during the period, increased to include dilutive potential common shares issuable upon the exercise of stock options that were outstanding during the period. For periods of net loss, diluted net loss per common share equals basic net loss per common share because common stock equivalents are not included in periods where there is a loss, as they are antidilutive. A reconciliation of the numerator and denominator in the basic and diluted net income per share calculation is as follows:

	Year Ended September 30,		
	2007	2006	2005
Numerator:			
Net income	$34,050,180	$ 1,958,903	$ 934,427
Denominator:			
Denominator for basic net income per common share — weighted average shares outstanding	11,449,646	11,068,102	10,932,246
Effect of dilutive stock options	822,526	597,890	496,984
Denominator for diluted net income per common share — weighted average shares outstanding	12,272,172	11,665,992	11,429,230
Net income per common share — basic	$ 2.97	$ .18	$ .09
Net income per common share — diluted	$ 2.77	$ .17	$ .08

Employee stock options of 30,000, 382,000 and 648,000 for fiscal years 2007, 2006 and 2005, respectively, have been excluded from the diluted net income per common share calculations because their exercise prices were greater than the average market price of the Company's common stock.

Business Segment

The Company conducts its business within one business segment which is defined as developing, manufacturing and marketing urinary continence and urinary drainage care products.

New Accounting Pronouncements

In July 2006, the Financial Accounting Standards Board ("FASB") issued FASB Interpretation No. 48, as amended, *Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement 109* ("FIN 48"), which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in our financial statements only if the position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of fiscal 2008, with the cumulative effect of the change in accounting principle recorded as an adjustment

to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on its consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS 157"). SFAS 157 establishes a single authoritative definition of fair value, establishes a framework for measuring fair value, and expands disclosure requirements pertaining to fair value measurements. The original pronouncement of SFAS 157 was effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. On a recent meeting, the FASB agreed to defer the effective date of this pronouncement and has agreed to issue additional guidance on specific related topics. The Company will continue to evaluate the impact that this guidance, as amended, will have on its results of operations and financial position. Based on the Company's understanding of the original pronouncement, the impact would have been immaterial.

In September 2006, the SEC staff issued Staff Accounting Bulletin 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* ("SAB 108"). SAB 108 requires that public companies utilize a "dual-approach" to assessing the quantitative effects of financial misstatements. This dual approach includes both an income statement focused assessment and a balance sheet focused assessment. The Company adopted SAB 108 in fiscal 2007 without any impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated financial position and results of operations.

In June 2006, the FASB ratified Emerging Issues Task Force ("EITF") Issue No. 06-03, "*How Taxes Collected form Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement (That Is, Gross Versus Net Presentation).*" EITF 06-03 requires companies to disclose the amount of taxes assessed by a governmental authority and recorded on a gross basis in interim and annual financial statements. The Company will be required to adopt EITF 06-03 as of October 1, 2007. The Company does not expect that the adoption of EITF 06-03 will have a material impact on its results of operations or cash flows.

3. Other Income

During the fiscal year ended September 30, 2007, the Company recorded $38,855,000 of other income, consisting primarily of two cash settlements. The first occurred on November 20, 2006, when the Company reached a settlement with Premier with respect to the lawsuit the Company initiated in February 2004 against certain GPOs and individual defendants alleging anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters. Under the settlement agreement, Premier paid the Company $8,825,000 (net $5,155,000 after payment of attorneys' fees and expenses) and was dismissed from the lawsuit. The second occurred on December 14, 2006, when the Company reached a settlement with C.R. Bard, Inc., whereby C.R. Bard, Inc. paid the Company $49,000,000 (net $33,450,000 after payment of attorneys' fees and expenses) and was released from the lawsuit.

4. Inventories

Inventories are summarized as follows:

	September 30, 2007	September 30, 2006
Raw materials	$1,762,593	$1,807,706
Work-in-process	3,202,035	1,603,912
Finished goods	2,851,288	1,312,978
Reserve for inventory obsolescence	(117,027)	(82,018)
	$7,698,889	$4,642,578

5. Finite Life Intangible Assets

Finite life intangible assets were as follows:

		September 30, 2007			September 30, 2006		
	Estimated Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net Value	Gross Carrying Amount	Accumulated Amortization	Net Value
Trademarks	8 to 15	$5,423,000	$540,233	$4,882,767	$5,423,000	$135,056	$5,287,944
Supply agreement	5	634,000	169,070	464,930	634,000	42,270	591,730
Customer relationships	20	2,650,570	176,705	2,473,865	2,431,000	40,517	2,390,483
Totals		$8,707,570	$886,008	$7,821,562	$8,488,000	$217,843	$8,270,157

Amortization expense related to these assets was as follows:

Year ended September 30, 2007	$668,165
Year ended September 30, 2006	$217,843

Estimated annual amortization expense for these assets over the next five years is as follows:

2008	$653,427
2009	$653,427
2010	$653,427
2011	$611,257
2012	$526,617

6. Shareholders' Equity

Stock Options

On November 17, 2006, the Company completed a 2:1 stock split. All numbers presented below reflect shares and prices post split.

Under the terms of the 1991 Stock Option Plan, the Board of Directors may grant employee incentive stock options equal to fair market value of the Company's Common Stock or employee non-qualified options at a price which cannot be less than 85% of the fair market value. In August 1998, the 1991 Stock Option Plan was amended to increase by 600,000 shares the number of shares authorized for issuance to 2,000,000 shares. Per the terms of the 1991 Stock Option Plan, as of April 20, 2001, no new stock options may be granted under the 1991 Stock Option Plan.

The 1995 Non-Statutory Stock Option Plan authorizes the issuance of up to 100,000 shares of Common Stock. Per the terms of the 1995 Non-Statutory Stock Option Plan, no option may be granted with a term longer than ten

years. The vesting schedule for options granted under the 1995 Non-Statutory Stock Option Plan is determined by the Compensation Committee of the Company's Board of Directors. In September 1995, Medical Advisory Board members were granted options to purchase 24,000 shares of the Company's Common Stock at an exercise price of $7.875 per share. These 24,000 shares have now expired. In April 1999, one member of the Medical Advisory Board was granted options to purchase 12,000 shares of the Company's Common Stock at an exercise price of $5.06 per share.

In February 2001, the Company's shareholders approved the 2001 Stock Incentive Plan. Under the terms of the 2001 Stock Incentive Plan, 1,000,000 shares were authorized for issuance pursuant to grants of incentive stock options and non-qualified options. Per the terms of the 2001 Stock Incentive Plan, options may be granted with a term no longer than ten years. The vesting schedule and term for options granted under the 2001 Stock Incentive Plan is determined by the Compensation Committee of the Company's Board of Directors. In January 2006, the 2001 Stock Option Plan was amended to increase by 1,000,000 shares the number of shares authorized for issuance to 2,000,000 shares.

Option activity is summarized as follows:

	Shares Reserved For Grant	Options Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Life
Balance as of September 30, 2004	327,000	2,037,238	$ 4.30	5.5 years
Options granted	(210,000)	210,000	4.70	
Options exercised	—	(164,738)	2.84	
Options canceled	36,500	(36,500)	6.26	
1991 Plan — options canceled and not reissuable	(3,000)	—	2.35	
Balance as of September 30, 2005	150,500	2,046,000	$ 4.42	4.90 years
Increase in Authorized Shares	1,000,000			
Options granted	(210,000)	210,000	5.85	
Options exercised	—	(39,560)	3.07	
Options canceled	194,440	(194,440)	6.64	
1991, 1995 Plan — options canceled and not reissuable	(175,940)	—	6.85	
Balance as of September 30, 2006	959,000	2,022,000	$ 4.39	4.94 years
Options granted	(407,000)	407,000	11.69	
Options exercised	—	(645,666)	4.75	
Options canceled	6,000	(6,000)	10.70	
1991, 1995 Plan — options canceled and not reissuable	—	—	—	
Balance as of September 30, 2007	558,000	1,777,334	$ 5.90	5.73 years
Outstanding options exercisable at end of period		1,323,334	$ 4.96	4.77 years

During the year ended September 30, 2007, two of the Company's executives and one of its directors tendered an aggregate of 41,340 shares with a fair market value of $485,750 to the Company as consideration for the exercise

of 56,000 stock options with an exercise price of $485,750. The shares acquired by the Company were subsequently retired.

The number of stock options exercisable at September 30, 2007, 2006 and 2005 was 1,323,334, 1,698,000 and 1,674,000 at a weighted average exercise price of $4.96, $4.24 and $4.49 per share, respectively.

Shares available for future stock option grants to employees and directors under existing plans were 558,000 at September 30, 2007. At September 30, 2007, the aggregate intrinsic value of options outstanding was $10,490,436, and the aggregate intrinsic value of options exercisable was $6,568,153. Total intrinsic value of options exercised was $7,578,512 for the year ended September 30, 2007.

The following table summarizes our nonvested stock option activity for the year ended September 30, 2007:

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested stock options at beginning of period	324,000	$2.97
Granted	407,000	8.03
Vested	(271,000)	5.29
Canceled	(6,000)	6.30
Nonvested stock options at end of period	454,000	$6.07

As of September 30, 2007, $1,413,271 of unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately fourteen months.

The weighted average fair value of options granted in 2007, 2006 and 2005 was $8.03, $3.40 and $2.67 per share, respectively. The exercise price of options outstanding at September 30, 2007 ranged from $2.17 to $12.30 per share as summarized in the following table:

Range of Exercise Prices	Number Outstanding at 9/30/07	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share — Total Options Outstanding	Number Exercisable at 9/30/07	Weighted Average Exercise Price Per Share — Options Exercisable
$0.00 — $5.00	1,051,334	4.7 years	$ 3.32	906,834	$ 3.31
5.01 — 10.00	364,000	5.2 years	6.33	266,500	6.46
10.01 — 15.00	332,000	9.2 years	12.24	150,000	12.30
15.01 — 20.00	5,000	9.5 years	18.02	—	—
20.01 — 25.00	25,000	9.5 years	21.78	—	—
	1,777,334	5.7 years	$ 5.90	1,323,334	$ 4.96

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

The Black-Scholes option pricing model was used to estimate the fair value of stock-based awards with the following weighted-average assumptions for the years ended September 30:

	2007	2006
Dividend yield	0%	0%
Expected volatility	48%	54%
Risk-free interest rate	4.11%	4.33%
Expected holding period (in years)	6.19	6.69
Weighted-average grant-date fair value	$8.03	$3.40

The risk-free rate is based on a treasury instrument whose term is consistent with the expected life of our stock options. The expected volatility, holding period, and forfeitures of options are based on historical experience.

7. Income Taxes

Deferred income taxes are due to temporary differences between the carrying values of certain assets and liabilities for financial reporting and income tax purposes. Significant components of deferred income taxes are as follows:

	September 30,	
	2007	2006
Deferred income tax assets:		
Net operating loss carryforwards	$ —	$ 7,840,000
Research and development credit carryforwards	—	291,000
Allowance for doubtful accounts	21,034	20,000
Inventory reserves	42,505	30,000
Inventory capitalization	504,864	192,000
Accrued expenses	86,396	66,000
Deferred revenue	—	205,000
Nonqualified option expense	724,040	—
Restricted stock expense	34,199	—
Capital loss carryforward	37,602	—
Prepaid taxes on intercompany sales	206,956	—
Other	14,278	—
Valuation allowance	—	(7,108,000)
Total income tax deferred assets	1,671,874	1,536,000
Deferred income tax liability:		
Depreciation and amortization	207,283	305,000
Other	16,838	—
Net deferred income tax assets	$1,447,753	$ 1,231,000

The deferred tax amounts above have been classified in the accompanying balance sheets as follows:

	September 30, 2007	September 30, 2006
Current assets	$ 876,032	$ 53,000
Non current assets	571,721	1,178,000
	$1,447,753	$1,231,000

The Company records a valuation allowance to reduce the carrying value of its net deferred tax assets to the amount that is more likely than not to be realized. During 2004 all of the Company's taxable income was offset by available net operating loss ("NOL") carryforwards and management had recorded a $9.1 million valuation allowance against its deferred tax assets due to the uncertainty of the realization and timing of the benefits from those deferred tax assets as the Company had not achieved a sufficient level of sustained profitability. During 2005 management concluded that the Company had attained a sufficient level of sustained profitability to allow the valuation allowance to be reduced to reflect management's estimate of the amount of deferred tax assets that will be realized in the near term. Considering projected levels of future income as well as the nature of the net deferred tax assets, management reduced the valuation allowance by $454,000 during 2005 resulting an a corresponding income tax benefit in the statement of operations, and management further reduced the allowance by $777,000 in 2006 to reflect management's revised and increased estimates of future taxable income. During 2007, the Company's earnings were sufficient to determine it is more likely than not that all deferred tax assets will be realized and the valuation allowance was therefore reduced to zero. The Company utilized its entire $21.0 million net operating loss in the current year which reduced the overall effective state and federal income tax rates. As a result, the Company recorded $8.4 million for income tax expense.

The income before taxes and the provision for taxes for the years ended September 30, 2007, 2006, and 2005 consist of the following:

	September 30, 2007	September 30, 2006	September 30, 2005
Income before taxes:			
U.S.	$41,700,139	$ 836,990	$ 480,427
Non-U.S.	797,690	449,742	—
Total income before taxes	42,497,829	1,286,732	480,427
Provision for taxes:			
U.S.			
Current tax expense	$16,554,431	593,000	126,000
Deferred tax expense	(212,801)	(777,000)	(454,000)
Benefit of operating loss carryforwards	(8,140,581)	(593,000)	(126,000)
Total U.S.	8,201,049	(777,000)	(454,000)
Non-U.S.			
Current tax expense	236,275	104,824	—
Deferred tax expense	10,325	—	—
Total Non-U.S.	246,600	104,824	—
Total provision (benefit) for taxes	$ 8,447,649	$ (672,176)	$(454,000)

The reconciliation between the statutory federal income tax rate of 35% and the effective income tax rate for the years ended September 30 is as follows:

	2007	2006	2005
Statutory federal income tax rate	35%	34%	34%
Increase (decrease) in taxes resulting from:			
State taxes	2	3	3
Foreign taxes	1	8	—
Change in valuation allowance and utilization of net operating loss carryforward	(17)	(97)	(132)
Other	(1)	—	—
Effective income tax rate	20%	(52)%	(95)%

8. Related Party Transactions

The brother-in-law of the CEO and President, the Vice President of Production Technologies and a member of the board of directors of the Company has performed legal services for the Company. During the years ended September 30, 2007, 2006 and 2005, the Company incurred legal fees and expenses of approximately $34,000, $58,000 and $32,000, respectively, to such counsel for services rendered in connection with litigation and for general legal services. Management believes the fees paid for the services rendered to the Company were on terms at least as favorable to the Company as could have been obtained from an unrelated party.

9. Significant Customers

Significant customers, measured as a percentage of sales, are summarized as follows:

	September 30,		
	2007	2006	2005
Significant customers:			
Hollister	15%	16%	16%
Coloplast	13	9	—
Porges (subsidiary of Coloplast)	3	5	6
Total	31%	30%	22%

10. Employee Benefit Plan

The Company has a 401(k) plan covering employees meeting certain eligibility requirements. The Company currently matches employee contributions at a rate of 50% with a maximum match of 2.5% of salary. The total matching expense for the year ended September 30, 2007 was $70,817. There was no matching expense for the years ended September 30, 2006 and 2005.

11. Geographic Area Data

Sales related to customers in the United States, Europe and the rest of the world are as follows:

	September 30,		
	2007	2006	2005
Sales:			
United States	$13,925,808	$10,993,204	$ 8,441,565
Europe	16,777,866	8,383,854	5,164,633
Rest of world	1,959,413	2,288,779	2,335,451
Total	$32,663,087	$21,665,837	$15,941,649

Sales are attributed to countries based upon the address to which the Company ships products, as set forth on the customer's purchase order.

Long-lived assets of the Company are located in the United States and Europe as follows:

	September 30,	
	2007	2006
Long-lived assets:		
United States	$13,805,558	$13,107,044
Europe	9,872,648	9,160,671
Total	$23,678,206	$22,267,715

12. Acquisition of Assets from Mentor and Coloplast

On June 2, 2006, the Company, through its subsidiary Rochester Medical Limited, completed the acquisition of certain assets of Coloplast A/S ("Coloplast") and Mentor Medical Limited ("MML"), pursuant to an agreement dated May 17, 2006. The Company paid a cash purchase price of $9.3 million at closing, and agreed to pay an additional $5.3 million in equal installments over five years. As provided in the agreement, the Company acquired certain assets, including certain trademarks, related to sales of MECs in the United Kingdom. The assets also include MML's UK Dispensing Appliance Contractor License and its sales offices and warehouse facility in Lancing, England. The Company also agreed to purchase approximately $160,000 of inventory to be sold in the United Kingdom.

On June 2, 2006, the Company completed the acquisition of certain assets owned and used by Mentor Corporation ("Mentor") in its silicone MEC business. Pursuant to the Asset Purchase Agreement, the Company paid $750,000 for certain equipment and other tangible assets in Mentor's facility in Anoka, Minnesota, and purchased certain inventory, work-in-progress and raw materials for the production of silicone MECs for approximately $879,000; the Company also leased the Anoka facility from Mentor for a period of six months following the closing of the transactions. Upon the closing of the transactions, the existing Supply Agreement, Foley Catheter Sales and Distribution Agreement and MEC License and Sales Distribution Agreement (including, but not limited to the Patent License and Technology License thereunder) between the Company and Mentor were terminated.

Coloplast and the Company also entered into a separately negotiated Private Label Distribution Agreement under which the Company supplies silicone MECs to Coloplast, which will be sold under Coloplast's brands worldwide excepting the United Kingdom. The Private Label Distribution Agreement specifies annual minimum purchases of silicone MECs by Coloplast. Coloplast also supplies the Company with its requirements of latex MECs which the Company sells in the United Kingdom under its newly acquired Freedom® and Freedom Plus® brands.

The Company accounted for the acquisition under the purchase method of accounting in accordance with SFAS 141. Accordingly, the purchase price was allocated to the tangible and intangible assets acquired and

liabilities assumed based on the Company's estimates of fair value at the acquisition date. The Company engaged an independent valuation firm to assist in the determination of the fair values. The initial purchase price exceeded the amounts allocated to the tangible and intangible assets by approximately $5.5 million and this excess was classified as goodwill.

The following tables provide further information on the acquisition and allocations:

Purchase Price Summary

Category	Amount
Initial Cash Payment	$ 9,269,000
Cash payment for Inventories	936,000
Direct acquisition costs	653,000
Total cash paid	10,858,000
Seller financed debt	5,340,000
Total Consideration	$16,198,000

Value Assigned to Assets & Liabilities

Category	Amount
Current assets	$ 936,000
Property & Equipment	1,287,000
Identifiable Intangibles	8,488,000
Goodwill	5,487,000
Net Assets Acquired	$16,198,000

The pro forma unaudited results of operations for the years ended September 30, 2006 and 2005, assuming consummation of the purchase of the assets from Coloplast and MML as of October 1, 2004, are as follows:

	2006	2005
Net Sales	$26,634,721	$23,317,974
Net Income	3,295,002	3,566,626
Per share data:		
Basic earnings	$ 0.30	$ 0.33
Diluted earnings	$ 0.28	$ 0.31

The pro forma unaudited results do not purport to be indicative of the results which would actually have been obtained had the acquisition of assets been completed as of the beginning of the earliest period presented.

13. Line of Credit and Long-Term Debt

In June 2006, in conjunction with the asset purchase agreement with Coloplast, the Company entered into an unsecured loan note deed with Coloplast with an outstanding principal amount of $5,340,000. The promissory note is non-interest bearing payable in five equal installments of $1,068,000 payable annually on June 2. The Company has discounted the $5,340,000 note at 6.90% and reflects a $4,010,028 liability on its balance sheet.

On June 2, 2006, in conjunction with the financing of the transactions between the Company, Mentor, and Coloplast, the Company entered into a $7,000,000 credit facility with U.S. Bank National Association. The credit

facility consists of a $5,000,000 term loan payable in five years and accruing interest at a rate equal to 6.83%, and a revolving line of credit of up to $2,000,000, maturing annually beginning March 31, 2007, with interest payable monthly at a floating rate based on the quoted one-month LIBOR rate plus 1.60%. As of September 30, 2007, the Company had no borrowings under the revolving line of credit and the term loan had an outstanding balance of $3,905,681. The obligations of the Company are secured by assets of the Company, including accounts receivable, investments, general intangibles, inventory, and equipment. The term loan agreement and revolving credit agreement require the Company to comply with certain financial covenants, including a fixed charge coverage ratio and minimum working capital of $8 million, and restrict certain additional indebtedness and liens.

Aggregate maturities of long-term debt are as follows for the years ending September 30:

2008	$1,849,463
2009	2,080,744
2010	2,225,397
2011	1,760,105
Total	$7,915,709

14. Quarterly Results (Unaudited)

Summary data relating to the results of operations for each quarter of the years ended September 30, 2007 and 2006 follows (in thousands, except per share amounts):

	Three Months Ended			
	December 31	March 31	June 30	September 30
Fiscal year 2007:				
Net sales	$ 7,512	$8,347	$8,367	$8,437
Gross profit	3,736	4,427	4,449	4,392
Income from operations	290	957	927	693
Net income before taxes	38,810	1,243	1,231	1,213
Net income per common share — basic	$ 2.83	$ .09	$ .07	$ .06
Net income per common share — diluted	$ 2.59	$ .08	$ .06	$ .06
Fiscal year 2006:				
Net sales	$ 4,607	$4,874	$5,358	$6,826
Gross profit	1,602	1,559	1,996	3,452
Income (loss) from operations	257	(199)	212	1,125
Net income (loss) before taxes	311	(244)	226	993
Net income (loss) per common share — basic	$ .03	$ (.02)	$ .02	$ .09
Net income (loss) per common share — diluted	$ .03	$ (.02)	$ .02	$ .08

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the

Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are adequately designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in applicable rules and forms.

Management's Annual Report on Internal Control Over Financial Reporting. Management's report on our internal control over financial reporting is contained in Item 7 above. The report of McGladrey & Pullen LLP on our internal control over financial reporting is contained in Item 8 above.

Changes in Internal Control Over Financial Reporting. During our fourth fiscal quarter, there was no significant change made in our internal control over financial reporting (as defined in Rule 13(a) — 15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. Other Information

None.

PART III

ITEM 10. Directors, Executive Officers and Corporate Governance

The information with respect to the Board of Directors contained under the heading "Election of Directors", and information contained under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" in 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 September 30, 2007, is incorporated herein by reference. Information with respect to our executive officers is provided in Part I, Item 1.

We have adopted a code of ethics in compliance with applicable rules of the Securities and Exchange Commission that applies to all of our employees, including our principal executive officer, our principal financial officer and our principal accounting officer or controller, or persons performing similar functions. We have posted a copy of the code of ethics on our website, at www.rocm.com. We intend to disclose any amendments to, or waivers from, any provision of the code of ethics by posting such information on such website.

ITEM 11. Executive Compensation

The information contained under the heading "Executive Compensation" in 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 September 30, 2007, (except for the information set forth under the subcaption "Compensation Committee Report on Executive Compensation") is incorporated herein by reference.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

(a) Equity Compensation Plans. The following table provides information related to our equity compensation plans as of September 30, 2007:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders(1)	1,777,334	$5.90	470,000
Equity compensation plans not approved by security holders(2)	12,000	$5.06	88,000
Total	1,789,334	$5.89	558,000

(1) Includes shares issuable under our 1991 Stock Option Plan and 2001 Stock Incentive Plan.

(2) Includes shares issuable to persons other than our full-time officers or employees pursuant to the exercise of stock options granted under our 1995 Non-Statutory Stock Option Plan that do not qualify as "incentive stock options" within the meaning of Section 422 of the Code.

(b) Security Ownership. The information contained under the heading "Security Ownership of Certain Beneficial Owners and Management" in 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 September 30, 2007 is incorporated herein by reference.

ITEM 13. Certain Relationships and Related Transactions, and Director Independence

The information contained under the heading "Certain Relationships and Related Transactions" in 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 September 30, 2007 is incorporated herein by reference.

ITEM 14. Principal Accounting Fees and Services

The information contained under the heading "Audit Committee Report and Payment of Fees to Auditors" in 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 September 30, 2007, is incorporated herein by reference.

PART IV

ITEM 15. Exhibits and Financial Statement Schedules

(a)(1) The following financial statements are filed herewith in Item 8.

(i) Consolidated Balance Sheets as of September 30, 2007 and 2006.

(ii) Consolidated Statements of Operations for the years ended September 30, 2007, 2006 and 2005.

(iii) Consolidated Statement of Shareholders' Equity and Comprehensive Income for the years ended September 30, 2007 and 2006.

(iv) Consolidated Statements of Cash Flows for the years ended September 30, 2007, 2006 and 2005.

(v) Notes to Consolidated Financial Statements.

(a)(2) Financial Statement Schedules.

Schedule II — Valuation and Qualifying Accounts

Financial statement schedules other than those listed have been omitted since they are not required or are not applicable or the required information is shown in the financial statements or related notes.

(b) Exhibits

The following exhibits are submitted herewith:

3.1	Articles of Incorporation of the Company, as amended. (Incorporated by reference to Exhibit 3.1 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2006).
3.2*	Amended and Restated Bylaws of the Company, as amended.
4.1	Specimen of Common Stock Certificate. (Incorporated by reference to Exhibit 4.4 of Registrant's Annual Report on Form 10-KSB for fiscal year ended September 30, 1995).
10.1†	The Company's 1991 Stock Option Plan as amended (Incorporated by reference to Exhibit 4.5 of Registrant's Registration Statement on Form S-8, Registration Number 333-10261).
10.2†	Amendment to the Company's 1991 Stock Option Plan as amended (Incorporated by reference to Exhibit 4.3 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 1998).
10.3†	Employment Agreement, dated August 31, 1990 between the Company and Anthony J. Conway. (Incorporated by reference to Exhibit 10.13 of Registrant's Registration Statement on Form S-18, Registration Number 33-36362-C).
10.4†	Employment Agreement, dated August 31, 1990 between the Company and Philip J. Conway. (Incorporated by reference to Exhibit 10.14 of Registrant's Registration Statement on Form S-18, Registration Number 33-36362-C).
10.5†	Change of Control Agreement dated December 4, 1998, between the Company and Philip J. Conway (Incorporated by reference to Exhibit 10.3 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 1998).

10.6†	Change of Control Agreement dated November 21, 2000, between the Company and Anthony J. Conway. (Incorporated by reference to Exhibit 10.6 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.7†	Change of Control Agreement dated November 21, 2000, between the Company and Dara Lynn Horner. (Incorporated by reference to Exhibit 10.7 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.8†	Employment Agreement, dated November 16, 1998 between the Company and Dara Lynn Horner. (Incorporated by reference to Exhibit 10.8 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 1999).
10.9†	Change of Control Agreement dated November 21, 2000, between the Company and Martyn R. Sholtis. (Incorporated by reference to Exhibit 10.9 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.10†	Change of Control Agreement dated November 21, 2000, between the Company and David A. Jonas. (Incorporated by reference to Exhibit 10.10 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.11†	The Company's 2001 Stock Incentive Plan. (Incorporated by reference to Exhibit 10.1 of Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2006).
10.12	Form of Incentive Stock Option Agreement. (Incorporated by reference to Exhibit 10.10 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2006).
10.13	Form of Non-Incentive Stock Option Agreement. (Incorporated by reference to Exhibit 10.11 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2006).
10.14	Form of Restricted Stock Award (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on November 21, 2006).
10.15†	The Company's Fiscal 2007 Management Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 21, 2006).
10.16†	The Company's Fiscal 2008 Management Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 20, 2007).
10.17	Agreement, dated May 17, 2006, between Coloplast A/S, Coloplast Limited, Mentor Medical Limited, the Company and Rochester Medical Limited (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006).
10.18	Asset Purchase Agreement, dated May 27, 2006, by and between Mentor Corporation and the Company (Incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006).
10.19	Term Loan Agreement, dated May 26, 2006, between the Company and U.S. Bank N.A. (Incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006).
10.20	Revolving Credit Agreement, dated May 26, 2006, between the Company and U.S. Bank N.A. (Incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006).
10.21	First Amendment to Term Loan Agreement and Addendum and Revolving Credit Agreement, dated May 26, 2006 (Incorporated by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006).
21*	Subsidiaries of the Company
23.1*	Consent of McGladrey & Pullen LLP.
24*	Power of Attorney.
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a).
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a).
32.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(b).
32.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(b).

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* Filed herewith.

† Management contract or compensatory plan or arrangement required to be filed as an exhibit to Form 10-K pursuant to Item 15(c) of Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Rochester Medical Corporation

By: /s/ Anthony J. Conway
Anthony J. Conway
Chairman of the Board, President, Chief Executive Officer and Secretary

Dated: December 3, 2007

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title
/s/ Anthony J. Conway Anthony J. Conway	Chairman of the Board, President, Chief Executive Officer, and Secretary (principal executive officer)
/s/ David A. Jonas David A. Jonas	Chief Financial Officer and Treasurer (principal financial and accounting officer)
* Darnell L. Boehm	Director
* Peter R. Conway	Director
* Roger W. Schnobrich	Director
* Benson Smith	Director
*By /s/ David A. Jonas David A. Jonas *Attorney-in-Fact*	Dated: December 3, 2007

ROCHESTER MEDICAL CORPORATION
SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS AND RESERVES

COL. A	COL. B	COL. C		COL. D	COL. E
		Additions		(1),(2)	
Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts — Describe	Deductions — Describe	Balance at End of Period
Year ended September 30, 2007:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 55,540	$ 7,080	—	$ 4,707	$ 57,913
Allowance for inventory obsolescence	82,018	131,686	—	96,677	117,027
Year ended September 30, 2006:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 93,549	$ 6,128	—	$ 44,137	$ 55,540
Allowance for inventory obsolescence	100,000	85,993	—	103,976	82,018
Year ended September 30, 2005:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 73,445	$ 29,387	—	$ 9,283	$ 93,549
Allowance for inventory obsolescence	100,000	—	—	—	100,000

(1) Uncollectible accounts written off net of recoveries

(2) Obsolete inventory written off against the allowance

INDEX TO EXHIBITS

Exhibit	
3.2	Amended and Restated Bylaws of the Company, as amended.
21	Subsidiaries of the Company.
23.1	Consent of McGladrey & Pullen LLP
24	Power of Attorney
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)
32.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(b)
32.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(b)

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