2009 ANNUAL REPORT – Magic³™ | StrataNF™ | FemSoft®

Rochester Medical

AT LAST... AN INTERMITTENT CATHETER YOU CAN *BELIEVE* IN.

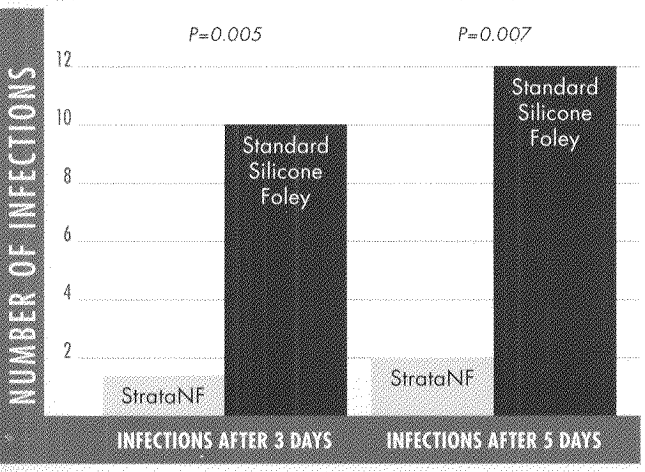
The all-silicone Magic³ intermittent catheter line is the latest example of our commitment to providing innovative solutions to address the needs of patients, caregivers, and clinicians.

"Your product is the best! Easy to use, great packaging. My confidence is higher because they're so much easier to use. Don't change a thing – they're perfect."

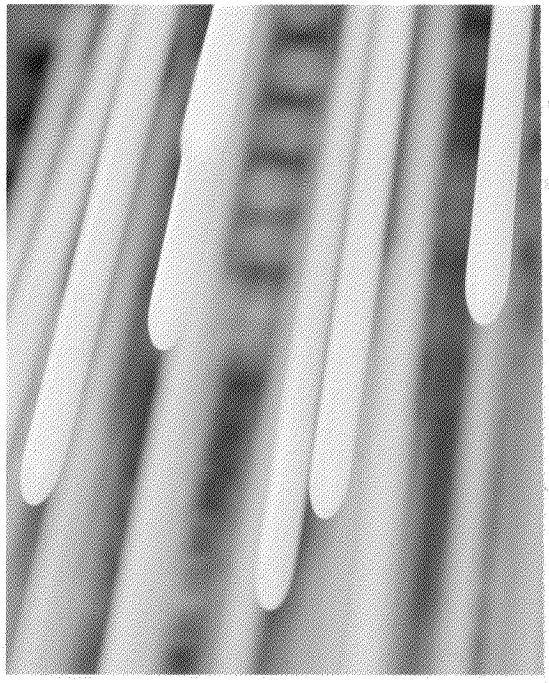
Carlsbad, CA

Proven Reduction of Bacterial CAUTI*

Catheter-associated urinary tract infections (CAUTI) are one of the most formidable infection prevention challenges in healthcare today.



A Pre-market clinical trial involving 344 patients demonstrated a 90% reduction in bacterial CAUTI at three days and an 83% reduction at five days for StrataNF when compared to a standard all-silicone Foley Catheter.

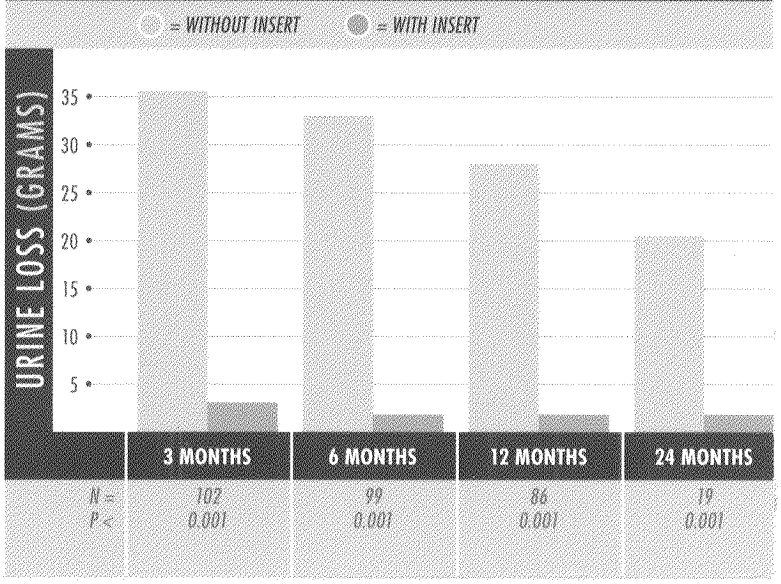


*Maki DG, Holcomb RG. A report on the randomized, controlled clinical trial of the nitrofurazone-impregnated, antibacterial, indwelling urinary catheter. April 30, 1997.

"The inserts have freed up my life. I can spend social evenings dancing and no problem. I don't even realize it's there."

FemSoft User, age 50

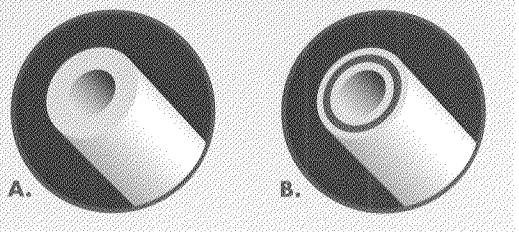
PAD-WEIGHING TEST *(over 24 month follow-up visit)*



GENTLE ON SENSITIVE TISSUE | EASY HANDLING | OPTIMAL DRAINAGE FLOW

magic^3™ INTERMITTENT CATHETER

with m^3 technology



Traditional single-layer catheters **(A.)** are rigid enough for easy handling, but can sometimes be painful and damaging to sensitive urethral tissue.

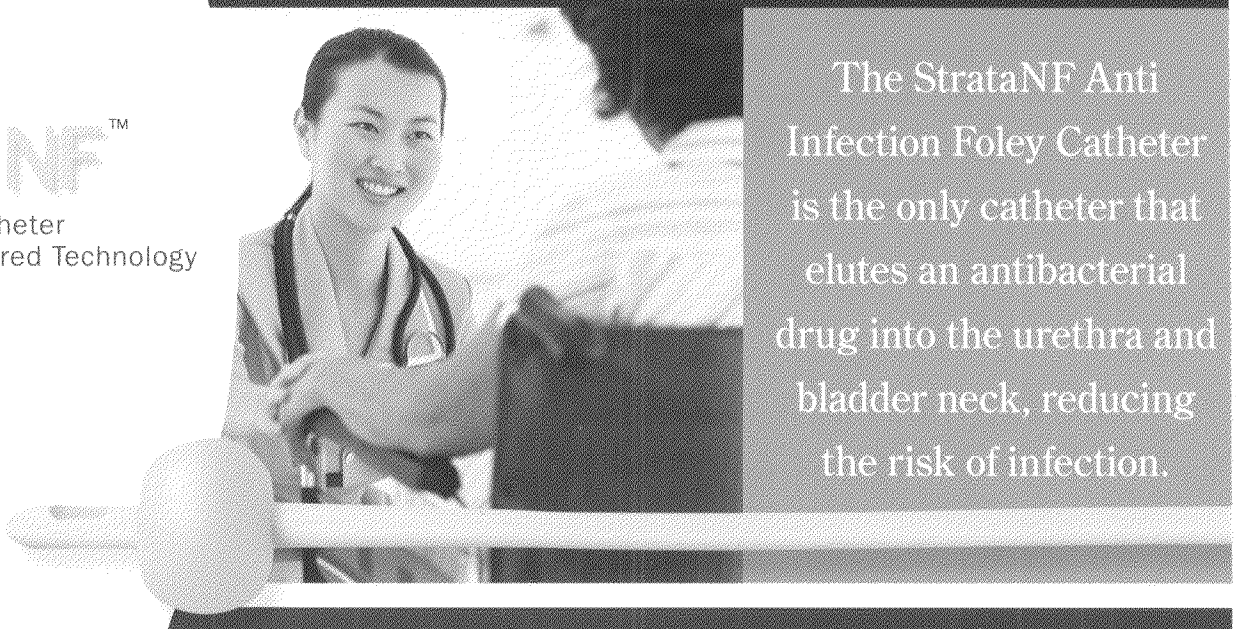
Our exclusive Magic^3 catheters **(B.)** are the first intermittent catheters designed from a unique composite of three distinct all-silicone layers, resulting in comfortable, easy, and reliable intermittent catheterization.

UNIQUELY DESIGNED TO PROTECT AGAINST THE TOUGHEST PATHOGENS.

Anti-Infection

Strata NF™

Silicone Foley Catheter
with Comfort Layered Technology

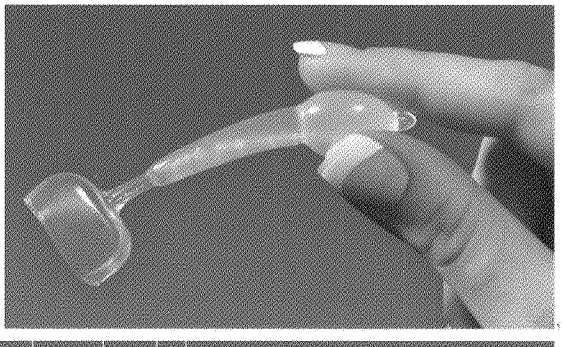


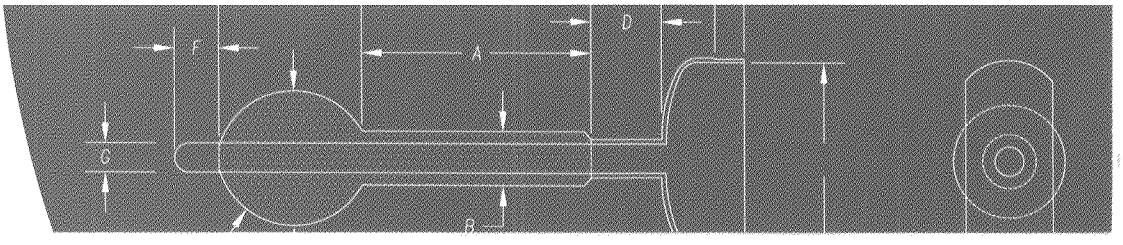
The StrataNF Anti Infection Foley Catheter is the only catheter that elutes an antibacterial drug into the urethra and bladder neck, reducing the risk of infection.

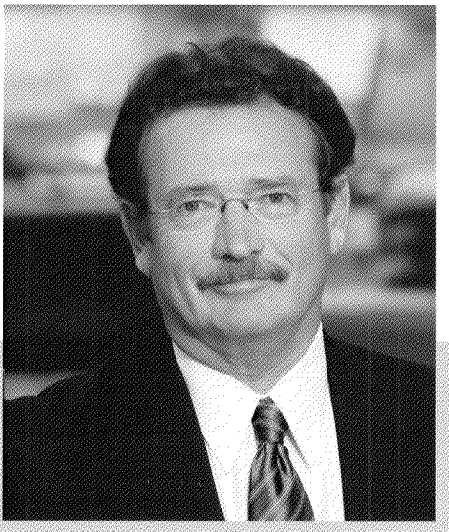
easy to insert & remove • comfortable to wear • safe & reliable

FemSoft® insert

Designed for comfort, the FemSoft Insert is a disposable, urethral insert so comfortable you'll hardly know it's there. A simple and gentle solution to stress urinary incontinence, the soft, sterile product prevents unintentional leakage – no pads, no worries.







ANTHONY J. CONWAY, *CEO & President*

to our SHAREHOLDERS:

Fiscal 2009 was a solid year for Rochester Medical. I am particularly pleased with three key areas of progress, each of which will provide for greater opportunity going forward.

Earlier this year we introduced a new generation of Intermittent Catheters. The Magic^3™ technology is being very well received in the United States and the United Kingdom and will be launched into mainland Europe in 2010. We are confident that the *Magic*^{3} triple layered all silicone construction, virtually friction-free surface, and optional antibacterial properties make it the finest Intermittent Catheter offering in the world marketplace.

We very recently introduced our new StrataSI™ and StrataNF™ Foley Catheters. This new product line offers all the advantages of silicone over latex along with our advanced anti-infection technology while providing the enhanced softness and gentleness of our new Comfort Layers. We believe this material and unique construction, along with the clinically proven infection control benefits, make Strata the clearly superior choice for patients requiring indwelling Foley Catheters.

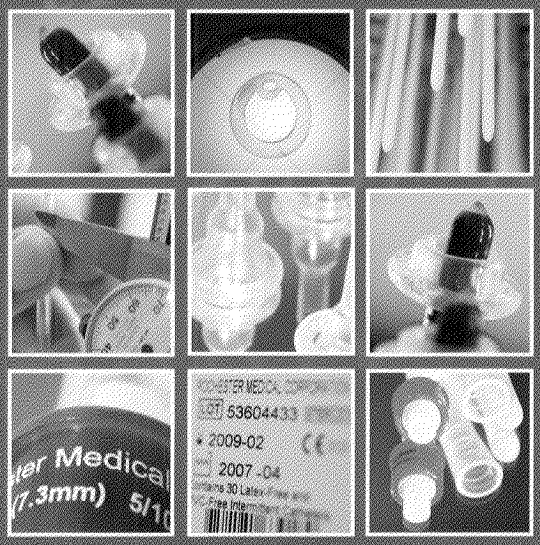
On another front, we also recently announced that our FemSoft® Insert device has received final approval for Medicare reimbursement in the United States, and also has been approved for reimbursement by the National Health Service in the United Kingdom. The reimbursement in both countries becomes effective in 2010.

Female stress incontinence is very common and causes significant quality of life issues for many millions of women throughout the world. Our unique *FemSoft* technology provides a comfortable, non-surgical means of managing the problem, and we believe the reimbursement decisions will provide many women access to this elegant and easy to use device.

Our talented and dedicated team of employees are very excited about the Company's future prospects. Progress made in 2009 positions us well for greater success going forward.

We recognize that, ultimately, it is you the shareholders who have made our progress possible. Thank you.

sincerely,



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

magic3™
INTERMITTENT CATHETER
with m³ technology

Anti-Infection
StrataNF™
Silicone Foley Catheter
with Comfort Layered Technology

FemSoft®
insert

2009 ROCHESTER MEDICAL

ROCM DIRECTORS:

Anthony J. Conway – A founder of the Company, Chairman of the Board, Chief Executive Officer, and President.

David A. Jonas – Chief Financial Officer, Secretary, and Treasurer.

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.

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.

ROCM EXECUTIVE OFFICERS:

Anthony J. Conway – Chief Executive Officer and President

David A. Jonas – Chief Financial Officer, Secretary, and Treasurer

Martyn R. Sholtis – Corporate Vice President

Philip J. Conway – Vice President, Production Technologies

Robert M. Anglin – Vice President, Quality & Regulatory

James M. Carper – Vice President, Marketing

CORPORATE HEADQUARTERS:

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

ph: 507-533-9600 *fax:* 507-533-9725 *web:* www.rocm.com

CORPORATE INFORMATION:

Independent Public Accountants:
Grant Thornton LLP
200 South Sixth Street – Suite 500 North
Minneapolis, Minnesota 55402 USA

Legal Counsel:
Dorsey & Whitney LLP
50 South Sixth Street – 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 of the Company's common stock as reported on the NASDAQ Stock Market (fiscal quarters).

FQ 2008	Quarter 1	Quarter 2	Quarter 3	Quarter 4
fiscal high	$18.02	$13.98	$13.27	$14.61
fiscal low	$11.07	$9.24	$10.42	$9.90
FQ 2009	**Quarter 1**	**Quarter 2**	**Quarter 3**	**Quarter 4**
fiscal high	$15.58	$15.23	$14.15	$13.42
fiscal low	$10.51	$9.05	$9.74	$11.83

Form 10-K Availability:
Copies of the Company's Form 10-K for the 2009 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

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, 2009

☐ **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:

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock without par value	Nasdaq Global Market

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 check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐ Smaller reporting company ☐
(Do not check if a smaller reporting company)

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 common equity held by non-affiliates based upon the closing Nasdaq sale price on March 31, 2009 was $105,597,255.

Number of shares of common stock outstanding on December 1, 2009 was 12,192,867 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's Proxy Statement for its 2010 Annual Meeting of Shareholders are incorporated by reference in Part III.

Table of Contents

PART I		3
ITEM 1.	Business	3
ITEM 1A.	Risk Factors	12
ITEM 1B.	Unresolved Staff Comments	19
ITEM 2.	Properties	19
ITEM 3.	Legal Proceedings	19
ITEM 4.	Submission of Matters to a Vote of Security Holders	19
PART II		20
ITEM 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	20
ITEM 6.	Selected Financial Data	22
ITEM 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	23
ITEM 7A.	Quantitative and Qualitative Disclosures about Market Risk.	36
ITEM 8.	Financial Statements and Supplementary Data	37
ITEM 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	61
ITEM 9A.	Controls and Procedures	61
ITEM 9B.	Other Information	61
PART III		62
ITEM 10.	Directors, Executive Officers and Corporate Governance	62
ITEM 11.	Executive Compensation	62
ITEM 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	62
ITEM 13.	Certain Relationships and Related Transactions, and Director Independence	62
ITEM 14.	Principal Accounting Fees and Services	62
PART IV		62
ITEM 15.	Exhibits, Financial Statement Schedules	62
	SIGNATURES	65
	INDEX TO EXHIBITS	67

PART I

ITEM 1. Business

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. We recently introduced *Magic3*™, an advanced line of silicone intermittent catheters. 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 new *Strata* brand of Foley catheters, which includes our *Strata 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, or 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 have adhesive applied to the full length of the sheath, and are 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 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"), 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 UTI. 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. 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.

We also have recently introduced an advanced line of intermittent catheters. Our *Magic3* catheters are the first intermittent catheters created from a composition of three distinct functional layers. Each of the three all-silicone laminates is uniquely formulated to independently address a particular product attribute required for comfortable, easy, and reliable intermittent catheterization. The catheter's special outer layer of nano-smooth soft silicone provides for an unparalleled hydrophilic surface which reduces trauma and maximizes patient comfort. The proprietary middle layer of firmer silicone supports confident handling for quick, simple catheter insertion. The innermost layer is designed to resist kinking and leverage the intrinsic hydrophobic (water-repelling) characteristics of silicone to enhance urine flow through the catheter. Similar to our *Personal Catheters*, the *Magic3* catheters are produced in three lengths for male, female, and pediatric use and in multiple diameters. The *Magic3* product line also incorporates all of our coating options and package configurations, including the advanced antibacterial and antibacterial hydrophilic technologies.

FemSoft Insert. The *FemSoft Insert* is a disposable device for the management of stress urinary incontinence in active women. It 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. The device can be simply inserted, worn and removed for voiding by most women. It requires no inflation, deflation, syringes or valving mechanisms. 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*. In September 2009, the *FemSoft Insert* was approved for inclusion in Part IX of the UK Drug Tariff as a prescription product that is reimbursable under the National Healthcare System. In November 2009, Medicare issued a specific reimbursement code which covers our *FemSoft Insert*. We believe the availability of National Healthcare System reimbursement and Medicare reimbursement, both of which commence in 2010, will help this unique device become an economically accessible and often preferred solution for incontinent women in the United Kingdom and in the United States.

Acute Care Products

Foley Catheters. We 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.

In September 2009, we introduced our new *StrataSI*™ and *StrataNF*™ silicone Foley catheters. The improved silicone design consists of a soft, pliable inner core surrounded by ultra-sort, ultra-smooth outer layers allowing for softness and flexibility we believe is unique in an all-silicone catheter. The *StrataNF* version includes a nitrofurazone anti-infective matrix within the silicone. Nitrofurazone is an effective broad-spectrum antibacterial agent which is released in a controlled dosage from the catheter directly into the urinary tract to retard the onset of infection.

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

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

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, but declining, portion of our revenues in the foreseeable future, particularly in non-United Kingdom international markets where currently we do not maintain a direct sales presence. Sales of products under the *Rochester Medical* brand comprised 67% of total sales in fiscal 2009, with private label sales representing 33% of total sales. In fiscal 2008 and fiscal 2007, private label sales comprised 32% and 41% of total sales, respectively. Sales to Hollister Incorporated ("Hollister") and to Coloplast under private label arrangements accounted for 12% and 10% of net sales for fiscal 2009, respectively.

In addition to direct sales to hospitals and other healthcare institutions, we have actively sought to sell our *Rochester Medical* brand products through 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 Group Purchasing Contract for urological products from Premier Purchasing Partners, L.P. ("Premier"). Premier is one of the largest GPOs in the United States with over $27 billion in contract purchases per year. Premier is owned by more than 200 leading not-for-profit hospitals and affiliated with 1,500 hospitals and 42,000 other healthcare sites. The contract includes our Foley catheters (including our infection control catheters), male external catheters, intermittent catheters, and urethral inserts. The contract became effective March 1, 2007, and has been extended through February 2013.

In August 2007, we announced that Novation, LLC ("Novation") awarded us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced infection control catheters. Novation provides contracting services to nearly 25,000 members of VHA, Inc. and the University HealthSystem Consortium, or UHC, and more than 15,000 customers of Provista (formerly HPPI). The contract has a three year term from the effective date of September 1, 2007. We have also been awarded a urological products contract with Broadlane Inc. This contract is effective January 1, 2010 and is a two year contract. Broadlane is a GPO whose clients include more than 915 acute care hospitals, more than 2,600 sub-acute care facilities and more than 18,000 physician practices.

We sell our *Rochester Medical* brand products and other companies' products direct to the patient in the United Kingdom through the *Script-Easy* program. U.K. residents can call a toll free number and order products for direct home delivery upon verification of a prescription from a doctor.

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 58%, 60% and 57% of total sales in 2009, 2008 and 2007, respectively.

Manufacturing

We design and build custom equipment to implement our manufacturing technologies and processes. Our two manufacturing facilities are located in Stewartville, Minnesota. In one building we produce our Foley catheters on one production line and our MECs on other lines. Our second building 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. In 2009, an FDA audit of our facilities was successfully completed.

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 that expires in June 2011, Coloplast supplies us with our requirement of latex male external catheters for sale in the United Kingdom under our *Freedom®* and *Freedom Plus®* brands.

Research and Development

In 2009 we introduced two new advanced product lines, our *Magic3* intermittent catheters and our *StrataSI* and *StrataNF* Foley catheters. Our *Magic3* intermittent catheters are created from a composition of three distinct functional layers designed to independently address a particular product attribute required for comfortable, easy, and reliable intermittent catheterization. Our *StrataSI* and *StrataNF* Foley catheters feature proprietary comfort-layered technology consisting of a soft, pliable inner core surrounded by ultra-soft, ultra-smooth outer layers.

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 products in development.

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.

Our patent rights provide us exclusive rights to use nitrofurazone as an antibacterial compound for catheters. Using our patented technology, nitrofurazone is incorporated into the structure of our catheter, and a controlled dosage of the antimicrobial compound is eluted from the catheter into the urethral tract. Unlike competitive catheters, in vitro tests show our antibacterial Foley catheter to be effective against a broad range of pathogens including a number of multi-drug resistant pathogens. Our Foley catheter is the only catheter currently on the market which the FDA allows the manufacturer to indicate on the packaging that it reduces the incidence of Catheter Associated UTI. We believe it is also the only non — latex Foley catheter shown to be effective against Catheter Associated UTI. We believe these to be competitive advantages of our antibacterial catheters.

All topical antibacterial compounds (including nitrofurazone) and all systemic antibiotics have some inherent risk of allowing development of resistant organisms and allowing overgrowth of organisms which are inherently resistant to the particular compound. Two of the reasons we selected nitrofurazone for use in our catheters, however, are that: (1) no known significant resistance to the compound has yet developed in over 50 years of use by the medical community; and (2) it has been found to be effective against a very broad spectrum of pathogens that can cause urinary tract infections. Although we have data from an extensive survey conducted in Spain from November 2003 to October 2004 on Foley catheters in chronically catheterized patients in an acute care setting (*i.e.*, within a hospital environment) that showed positive results for the use of nitrofurazone — impregnated catheters on a longer term basis (approximately 30 — 45 days of use), we have not conducted clinical trials in the extended care setting (*i.e.*, for personal, at — home use) and do not make clinical claims for our antibacterial intermittent catheters used in that setting.

Research and development expense for fiscal years 2009, 2008 and 2007 was $1,241,000, $1,044,000 and $943,000, 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 Incorporated, 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.

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 sought an unspecified amount of damages and injunctive and other relief. Beginning in November 2006 and concluding in January 2009, we reached a settlement with each of the defendants, resulting in aggregate settlement proceeds to us of $61,325,000 (net $39,605,000 after payment of attorneys' fees and expenses) and an Innovative Technology Contract with Novation. No further action is expected with respect to this lawsuit.

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 15 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, or 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 subject to FDA inspections 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 prohibit a manufacturer from marketing a medical 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. In 2009, an FDA audit of our facilities was successfully completed.

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 market authorization. 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, and the products we currently distribute into the EU display the required CE mark. 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 or cleared 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. The competitive position of certain of our products may be partially dependent upon the extent of reimbursement for our products.

Effective April 1, 2008, the four regional Durable Medical Equipment Medicare Administrative Contractors covering the United States implemented a new reimbursement policy for the use of intermittent catheters. The main policy change now allows an intermittent catheter user a maximum of 200 catheters per month instead of four catheters per month under the previous policy. We believe this is a very positive change in helping reduce urinary tract infections and improving the quality of life for intermittent catheter users. We expect the updated Medicare coverage policy will increase the usage of intermittent catheters in the U.S., although the scale and pace of the change are difficult to predict.

In November 2009, Medicare issued a specific reimbursement code which covers the *FemSoft Insert*. We believe the availability of Medicare reimbursement, which commences in 2010, will help this unique device become an economically accessible and often preferred solution for incontinent women in the United States.

In September 2009, the *FemSoft Insert* was approved for inclusion in Part IX of the UK Drug Tariff as a prescription product that is reimbursable under the National Healthcare System. 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.

Through a new Private Label Distribution Agreement with Coloplast, we supply silicone MECs to be sold under Coloplast's brands worldwide, excluding the United Kingdom, through June 2011. Through a Private Label Agreement with Hollister, we supply silicone MECs to be sold under the Hollister brand worldwide, excluding the United Kingdom, through December 2011.

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 foreseeable future, any material impact on our capital expenditures, earnings or competitive position.

Employees

As of September 30, 2009, we employed 253 full-time employees, of whom 169 were in manufacturing, 66 in marketing and sales and the remainder in 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	65	Chairman of the Board, Chief Executive Officer and President
Robert M. Anglin	42	Vice President, Quality and Regulatory
James M. Carper	58	Vice President, Marketing
Philip J. Conway	53	Vice President, Production Technologies
David A. Jonas	45	Director, Chief Financial Officer, Treasurer and Secretary
Martyn R. Sholtis	50	Corporate Vice President

Anthony J. Conway, one of our founders, has served as our Chairman of the Board, Chief Executive Officer and President since May 1988, and also served as our Secretary until November 2008 and as our Treasurer until September 1997. In addition to his duties as Chief Executive Officer, Mr. 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. Conway worked for twelve years for International Business Machines Corporation in various research and development capacities. Mr. Conway is one of the named inventors on numerous patent applications that have been assigned to us, of which to date over 20 resulted in issued U.S. patents and 32 have resulted in issued foreign patents.

Robert M. Anglin has served as our Vice President of Quality and Regulatory since November 2008. From December 2003 until November 2008, Mr. Anglin served as our Director of Quality and Regulatory with principal responsibility for our quality and regulatory compliance activities. From September 2000 until December 2003, Mr. Anglin served as our Director of Quality with principal responsibility for our quality management system. From June 1991 until September 2000, Mr. Anglin served in various operational, quality, and product development activities. Mr. Anglin holds a BS degree in Operations Management from Winona State University and holds various professional certifications from the Regulatory Affairs Professionals Society, American Society for Quality, and the APICS Association for Operations Management.

James M. Carper has served as our Vice President of Marketing since November 2008. Mr. Carper joined us in 1994 as a Regional Sales Manager and was promoted in 1996 to Director of Marketing, a position he held until September 2000. Mr. Carper ran his own marketing agency from 2000 to 2007 before rejoining us as our Marketing Director. Prior to Rochester Medical, he served as the Marketing Manager for urological products with Sherwood Medical.

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. Conway served as our Vice President of Operations. Mr. 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. Conway served as Plant and Production Manager of Arcon Corporation. Prior to joining Arcon, Mr. 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 over 20 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, as our Chief Financial Officer since May 2001, and as our Secretary since November 2008. Mr. Jonas was also elected to fill a vacancy in our Board of Directors in November 2008. 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.

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 and Philip J. Conway are brothers.

Recent Developments

In January 2009, we introduced *Magic3,* our advanced line of silicone intermittent catheters, which are the first intermittent catheters created from a composition of three distinct functional layers. Each of the three all-silicone laminates is uniquely formulated to independently address a particular product attribute required for comfortable, easy, and reliable intermittent catheterization.

In September 2009, we introduced our new *StrataSI* and *StrataNF* silicone Foley catheters. The improved silicone design consists of a soft, pliable inner core surrounded by ultra-sort, ultra-smooth outer layers allowing for softness and flexibility we believe is unique in an all-silicone catheter. The *StrataNF* version includes a nitrofurazone anti-infective matrix within the silicone.

In September 2009, the *FemSoft Insert* was approved for inclusion in Part IX of the UK Drug Tariff as a prescription product that is reimbursable under the National Healthcare System. In November 2009, Medicare issued a specific reimbursement code which covers our *FemSoft Insert.* We believe the availability of National Healthcare System reimbursement and Medicare reimbursement, both of which commence in 2010, will help this unique device become an economically accessible and often preferred solution for incontinent women in the United Kingdom and in the United States.

In November 2009, we were awarded a urological products contract with Broadlane Inc. This contract is effective January 1, 2010 and is a two year contract. Broadlane is a GPO whose clients include more than 915 acute care hospitals, more than 2,600 sub-acute care facilities and more than 18,000 physician practices.

Information Available on Our Website

We were incorporated in the State of Minnesota in 1988. 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 customers in fiscal 2009 represented approximately 34% 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. 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 under their brand names, and on the sales and marketing efforts of such entities. Private label sales arrangements with these entities are likely to continue to be a significant, but declining, portion of our revenues in the future. We also rely on various independent distributors to sell our products. There can be no assurance that our private label 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. Worldwide private label sales increased 1.8% in fiscal 2009 compared to fiscal 2008, and represented 33% of total sales. 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, or our failure to replace such private label sales with sales under the *Rochester Medical* brand, could significantly reduce our future sales revenue.

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 our infection control catheters), male external catheters, intermittent catheters, and urethral inserts, and has been extended through February 2013. In August 2007, we announced that Novation, LLC awarded us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced infection control catheters. The contract has a three-year term from the effective date of September 1, 2007. In November 2009, we were awarded a urological products contract with Broadlane Inc. This contract is effective January 1, 2010 and is a two year contract. 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 sought an unspecified amount of damages and injunctive and other relief. Beginning in November 2006 and concluding in January 2009, we reached a settlement with each of the defendants, resulting in aggregate settlement proceeds to us of $61,325,000 (net $39,605,000 after payment of attorneys' fees and expenses) and an Innovative Technology Contract with Novation. No further action is expected with respect to this lawsuit.

Our products may not succeed in the market

We have several products, including the antibacterial hydrophilic and antibacterial hydro intermittent catheters 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 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

Until fiscal 2003, we experienced net losses. Net income for the fiscal years ended September 30, 2009, 2008 and 2007 was $109,000, $759,000 and $34,050,000 (which included approximately $31,000,000 from lawsuits net of taxes), respectively. 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 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 2009, 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 reimbursement from third-party payors, and cost containment measures could decrease the demand for our products and the prices that our customers are willing to pay for those products

Our products are purchased principally by healthcare providers that typically bill various third-party payors, such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of customers to obtain appropriate reimbursement for their services and the products they provide from government and third-party payors is critical to the success of medical device companies because it affects which products customers purchase and the prices they are willing to pay. Reimbursement varies from country to country and can significantly impact the acceptance of new technology. Even when we develop a promising new product, we may find limited demand for the product unless reimbursement approval is obtained from private and governmental third-party payors.

Major third-party payors for healthcare provider services in the United States and abroad continue to work to contain healthcare costs through, among other things, the introduction of cost containment incentives and closer scrutiny of healthcare expenditures by both private health insurers and employers. Initiatives to limit the growth of healthcare costs, including price regulation, are also underway in several countries in which we do business. Implementation of healthcare reforms in the United States and in significant overseas markets such as the United Kingdom and other countries within the European Union may limit the price of, or the level at which, reimbursement is provided for our products and adversely affect both our pricing flexibility and the demand for our products. Healthcare providers may respond to such cost-containment pressures by substituting lower cost products or other therapies for our products.

Further legislative or administrative reforms to the U.S. or international reimbursement systems that significantly reduce reimbursement for procedures using our medical devices or deny coverage for such procedures, or adverse decisions relating to our products by administrators of such systems in coverage or reimbursement issues, would have an adverse impact on the products, including clinical products, purchased by our customers and the prices our customers are willing to pay for them. This in turn would have an adverse effect on our financial condition and results of operations.

The adoption of certain types of healthcare reform programs in the United States may adversely affect our business, financial condition and results of operations.

Recently, there have been, and there could continue to be, numerous proposals to implement significant reforms to the healthcare system in the United States. Members of Congress have introduced legislation that will, among other things, reduce Medicare provider reimbursement rates, introduce and/or pilot various new patient care and payment models, including Medicare payment bundling and gain-sharing, and base reimbursement policies and rates on clinical outcomes and the comparative effectiveness and costs of different treatment technologies and modalities. Legislation passed in the U.S. House of Representatives on November 7, 2009 and a draft bill released in the U.S. Senate also include an excise tax on all medical devices, requiring the medical device industry to pay an estimated $20 billion to $40 billion in additional taxes over a period of at least 10 years. Various healthcare reform proposals have also emerged at the state level. We cannot predict what healthcare initiatives and subsequent

regulations, if any, will be implemented at the federal or state level, or the effect any future legislation or regulation will have on us. However, if significant changes are made to the healthcare system in the United States, those changes may lower or eliminate reimbursements for our products, impact the demand for our products or prices at which we sell our products, and/or increase our cost of doing business, any of which could have a material adverse effect on our business, financial condition and results of operations.

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.

Our operations are subject to environmental, health and safety laws and regulations that could require us to incur material costs.

Our operations are subject to environmental, health and safety laws and regulations concerning, among other things, the generation, handling, transportation and disposal of hazardous substances or wastes, the cleanup of hazardous substance releases, and emissions or discharges into the air or water. We have incurred and expect to incur expenditures in the future in connection with compliance with environmental, health and safety laws and regulations. New laws and regulations, violations of these laws or regulations, stricter enforcement of existing requirements, or the discovery of previously unknown contamination could require us to incur costs or become the basis for new or increased liabilities that could be material.

Our international sales and operations expose us to foreign currency fluctuations and additional risks and uncertainties that could adversely affect our results of operations

Sales outside the U.S. accounted for approximately 58% of our net sales in fiscal 2009. We anticipate that sales from international operations will continue to represent a significant portion of our total sales. We are currently marketing our products in approximately 80 countries around the world 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 three distributors in international markets. We cannot assure you that international distributors for our products will devote adequate resources to selling and servicing our products. Additionally, we face currency and other risks associated with our international

sales. Through our subsidiary Rochester Medical Limited, we are exposed to foreign currency exchange rate fluctuations due to transactions denominated primarily in British pounds, which may potentially reduce the U.S. dollars we receive for sales denominated in British pounds and/or increase the U.S. dollars we report as expenses in British pounds, thereby affecting our reported consolidated revenues and net earnings. Fluctuations between the currencies in which we do business have caused and will continue to cause foreign currency transaction gains and losses. We cannot predict the effects of currency exchange rate fluctuations upon our future operating results because of the volatility of currency exchange rates.

In addition to foreign currency exchange rate fluctuations, there are a number of additional risks associated with our international operations, including those related to:

- 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;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in collecting accounts receivable and longer collection periods;
- unexpected changes in regulatory requirements, surtaxes, tariffs, customs duties or other trade barriers;
- weaker intellectual property rights protection in some countries; 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.

Weakness in the United States and international economies may continue to adversely affect our business

We experienced a challenging economic environment in fiscal 2009 in which some customers in geographic regions in which we operate reduced or deferred purchases of our products. Although there are some indications that the economy in the United States has begun to recover, the U.S. economy may not recover or may deteriorate further, which could continue to adversely affect our operations and results in fiscal 2010. The economies of Europe and other regions may also remain distressed well into 2010 or longer, which could continue to adversely affect our operations and results in fiscal 2010.

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 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. Our ability to obtain financing for acquisitions or other general corporate and commercial purposes will depend on our operating and financial performance and is also subject to prevailing economic conditions and to financial, business and other factors beyond our control. Recently, global credit markets and the financial services industry have been experiencing a period of unprecedented turmoil characterized by the bankruptcy, failure or sale of various financial institutions, a general tightening of credit, and an unprecedented level of market intervention from the United States and other governments. These events have adversely affected the U.S. and world economy, and may

adversely affect the availability and cost of financing. 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 consist 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 current needs. Our manufacturing facility in Stewartville, Minnesota could be expanded if the need arises.

ITEM 3. Legal Proceedings

We were a plaintiff in a lawsuit initiated in February 2004 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 alleged anti-competitive conduct against the defendants in the markets for standard and anti-infection Foley catheters as well as urethral catheters, and sought 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 that 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. Under the settlement agreement, Novation awarded 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.

In January 2009, we announced that we had reached a settlement with Covidien Ltd,., Tyco International (US), Inc. and Tyco Health Care Group, L.P. whereby Covidien Ltd. Paid the Company $3,500,000 (net $1,000,000 after payment of attorney's fees and expenses) and was dismissed from the lawsuit. No further action is expected with respect to this lawsuit.

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, 2009.

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.

	High	Low
Fiscal 2008		
First Quarter	$18.02	11.07
Second Quarter	13.98	9.24
Third Quarter	13.27	10.42
Fourth Quarter	14.61	9.90
Fiscal 2009		
First Quarter	$15.58	10.51
Second Quarter	15.23	9.05
Third Quarter	14.15	9.74
Fourth Quarter	13.42	11.83

Repurchases of Equity Securities

In December 1999, the Board of Directors authorized a share repurchase program. Up to 2,000,000 shares may be repurchased from time to time on the open market, or pursuant to negotiated or block transactions, in accordance with applicable Securities and Exchange Commission regulations. No time limit has been placed on the duration of the share repurchase program and it may be conducted over an extended period of time as business and market conditions warrant. We also may discontinue the share repurchase program at any time. We intend to fund such repurchases with currently available funds. On March 3, 2009, we announced our intention to repurchase some of our outstanding common shares pursuant to our previously authorized share repurchase program. During the three months ended September 30, 2009, no shares were repurchased. During fiscal 2009, we repurchased 110,653 shares of common stock pursuant to this program. As of September 30, 2009, there remained 1,847,347 shares that may be purchased under the 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).

Holders

As of December 1, 2009, we had 120 shareholders of record. Such number of record holders does not reflect shareholders who beneficially own common stock in nominee or street name.

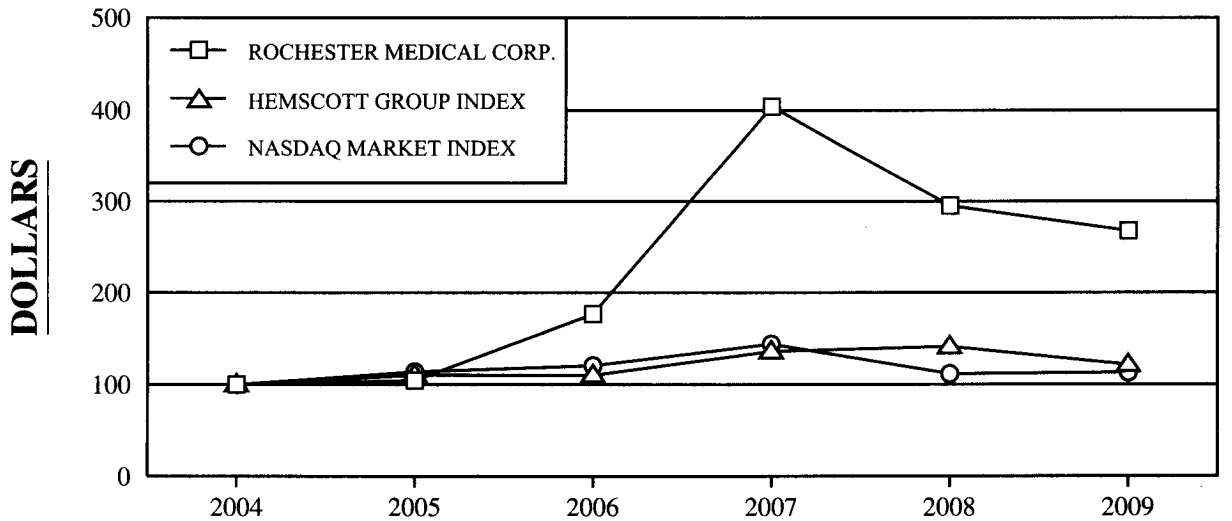
Dividends

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, 2009. The comparison assumes $100 was invested on October 1, 2004 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.

COMPARISON OF 5-YEAR CUMULATIVE TOTAL RETURN
AMONG ROCHESTER MEDICAL CORP.,
NASDAQ MARKET INDEX AND HEMSCOTT GROUP INDEX



ASSUMES $100 INVESTED ON OCT. 1, 2004
ASSUMES DIVIDEND REINVESTED

	Fiscal Year Ending					
	9/30/04	9/30/05	9/30/06	9/30/07	9/30/08	9/30/09
Rochester Medical Corporation	$100	$104.34	$176.50	$404.23	$295.32	$268.15
Hemscott Group Medical Instruments and Supplies Index	100	110.37	110.09	136.06	141.30	121.32
Nasdaq Market Index	100	113.76	120.51	144.01	111.56	112.97

ITEM 6. Selected Financial Data

The following selected financial data of Rochester Medical Corporation as of September 30, 2009 and for the year ended September 30, 2008, is derived from, and should be read together with, our consolidated financial statements audited by Grant Thornton, LLP, our current independent auditors, and the financial data for the year ended September 30, 2007 are derived from, and should be read together with, our consolidated financial statements audited by McGladrey & Pullen LLP, our former independent auditors, included elsewhere in this Form 10-K. The following selected financial data as of September 30, 2007, 2006 and 2005 and for the fiscal years ended September 30, 2006 and 2005 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,				
	2009	2008	2007	2006	2005
	(In thousands, except for per share data)				
Net sales	$34,799	$35,192	$32,663	$21,666	$15,942
Cost of sales	17,973	18,484	15,619	13,057	10,330
Gross profit	16,826	16,708	17,044	8,609	5,612
Operating expenses:					
Marketing and selling	10,327	9,499	6,490	3,109	2,398
Research and development	1,241	1,044	943	760	730
General and administrative	6,007	6,658	6,743	3,345	2,127
Total operating expenses	17,575	17,201	14,176	7,214	5,255
Income (loss) from operations	(749)	(493)	2,868	1,395	357
Other income	1,200	1,240	38,855	—	—
Interest income (expense), net	24	(566)	775	(108)	124
Net income before income tax	475	181	42,498	1,287	481
Income tax benefit (expense)	(366)	578	(8,448)	672	454
Net income	$ 109	$ 759	$34,050	$ 1,959	$ 935
Net income per common share — basic	$ .01	$ .06	$ 2.97	$ .18	$ .09
Net income per common share — diluted	$ .01	$ .06	$ 2.77	$ .17	$ .08
Weighted average number of common shares outstanding — basic	12,045	11,816	11,450	11,068	10,932
Weighted average number of common shares outstanding — diluted	12,640	12,577	12,272	11,666	11,430

	As of September 30,				
	2009	2008	2007	2006	2005
			(In thousands)		
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$36,262	$37,002	$37,137	$ 2,907	$ 6,416
Working capital	48,552	48,772	46,325	7,664	12,671
Total assets	75,965	76,983	75,495	35,952	22,209
Long-term debt and capital lease obligations	1,076	4,046	6,066	7,563	98
Retained earnings (accumulated deficit)	14,833	14,724	13,964	(20,086)	(22,045)
Total shareholders' equity	68,820	67,699	64,509	23,097	20,288

No dividends were declared or paid in any year from 2005 to 2009.

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. We sell our products both in the domestic market and internationally. International sales accounted for approximately 58% and 60% of total sales in the fiscal years ending September 30, 2009 and 2008, respectively.

We sell our products in the United States under the *Rochester Medical* brand name through a thirteen-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 sixteen-person direct sales force. We also rely on various independent distributors to sell our products. The primary markets for our products are distributors, extended care facilities and individual hospitals and healthcare institutions.

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. Private label sales arrangements with these entities are likely to continue to be a significant, but declining, percentage of our revenues in the future, while we continue to establish our own market presence under the *Rochester Medical* brand name. Private label sales represented 33% of total sales in fiscal 2009, compared to 32% of total sales in fiscal 2008.

For fiscal 2009, we increased the investment in our sales and marketing programs, primarily through cash generated from current operations, to support *Rochester Medical* branded sales growth in the U.S. and Europe. Our advanced products will eventually contribute a higher profit margin than our base products, and our *Rochester Medical* branded products contribute a higher profit margin than private label sales, particularly branded sales in the United Kingdom and elsewhere in Europe. Increasing our percentage of sales of branded products versus private label sales over time will have a positive impact on our gross margin. Branded sales accounted for 67% of total sales for the year ended September 30, 2009, compared to 68% for the prior year. Advanced products accounted for 15% of total sales for the year ended September 30, 2009, compared to 13% for the prior year.

Net sales for our fiscal year ended September 30, 2009 were $34.8 million, a decrease of $0.4 million from $35.2 million in the prior fiscal year. The decrease in net sales resulted from a 2% decrease in branded sales for the fiscal year, partially offset by a 2% increase in private label sales. The decrease in branded sales resulted from a decrease in sales of base products in the United Kingdom primarily due to fluctuations in the foreign currency exchange rate between the US dollar and the British pound, partially offset by an increase in sales of advanced products in the U.S. and internationally. The aggregate effect of exchange rate fluctuations for the year resulted in a decrease of $2.8 million in net branded sales.

Our five largest customers in fiscal 2009 represented approximately 34% 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.

We also sell our *Rochester Medical* brand products and other companies' products direct to the patient in the United Kingdom through the *Script-Easy* program. U.K. residents can call a toll free number and order products for direct home delivery upon verification of a prescription from a doctor.

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 products.

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

- In February 2004, we brought suit against certain Group Purchasing Organizations (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 sought an unspecified amount of damages and injunctive and other relief. Beginning in November 2006 and concluding in January 2009, we reached a settlement with each of the defendants, resulting in aggregate settlement proceeds to us of $61,325,000 (net $39,605,000 after payment of attorneys' fees and expenses) and an Innovative Technology Contract with Novation. No further action is expected with respect to this lawsuit.

- In November 2006, we announced we had been awarded a national Group Purchasing Contract for urological products from Premier Purchasing Partners, L.P. ("Premier"). Premier is one of the largest GPOs in the United States with over $27 billion in contract purchases per year. Premier is owned by more than 200 leading not-for-profit hospitals and affiliated with more than 1,500 hospitals and 42,000 other healthcare sites. The contract includes our Foley catheters (including our infection control catheters), male external catheters, intermittent catheters, and urethral inserts. The contract became effective March 1, 2007, and has been extended through February 2013.

- As mentioned above, Novation awarded us an Innovative Technology Contract for our urological catheter products and related accessories, including our advanced infection control catheters. Novation provides contracting services to nearly 25,000 members of VHA, Inc. and the University HealthSystem Consortium, or UHC, and more than 15,000 customers of Provista (formerly HPPI). The Innovative Technology Contract has a three year term from the effective date of September 1, 2007.

- In November 2009, we were also awarded a urological products contract with Broadlane Inc. This contract is effective January 1, 2010 and is a two year contract. Broadlane is a GPO whose clients include more than 915 acute care hospitals, more than 2,600 sub-acute care facilities and more than 18,000 physician practices.

- Effective April 1, 2008, the four regional Durable Medical Equipment Medicare Administrative Contractors covering the United States implemented a new reimbursement policy covering the use of intermittent catheters. The main policy change now allows an intermittent catheter user a maximum of 200 catheters per month instead of four catheters per month under the previous policy. We believe this is a very positive change in helping reduce urinary tract infections and improving the quality of life for intermittent catheter users. We expect the updated Medicare coverage policy will increase the usage of intermittent catheters in the U.S., although the scale and pace of the change are difficult to predict.

- On May 15, 2008, we announced that the United Kingdom's Association for Continence Advice (ACA) awarded us its trophy for best product for our Hydrosil Discreet intermittent catheter. There were seventeen entries competing for the ACA "Look Good, Feel Good Award" at the ACA annual conference, including entries from our major competitors. The ACA is a membership organization for health and social care professionals concerned with the progression of care for continence.

- On June 12, 2008, we announced that Rochester Medical was a winner of a Premier Performance Award, presented by the Premier healthcare alliance's Purchasing Partners unit. We were one of 54 of more than 800 Premier contracted suppliers to receive the Performance Award, which recognizes the efforts of contracted suppliers to meet or exceed Premier members' service expectations. In selecting recipients, satisfaction and performance data are collected and scored over four successive calendar quarters. Organizations scoring 80 percent or higher earn the Performance Award.

- In January 2009, we introduced *Magic3,* our advanced line of silicone intermittent catheters, which are the first intermittent catheters created from a composition of three distinct functional layers. We initiated a

comprehensive marketing campaign by rolling out the *Magic3* intermittent catheter line in the U.S. with introduction to our distribution partners and targeted clinical call points. The marketing campaign encompassed clinicians as well as catheter users. Concurrently, the new product line was introduced by Rochester Medical Limited in the United Kingdom and Europe where a similar comprehensive marketing campaign was launched.

Our net income for fiscal 2009 was $109,000, or $0.01 per diluted share, compared to $759,000, or $0.06 per diluted share in fiscal 2008. Net income was impacted by our increased strategic investment in sales and marketing programs and increased costs in research and development of new products. Additionally, we experienced a challenging economic environment in fiscal 2009 in which some customers in geographic regions in which we operate reduced or deferred purchases of our products.

As of September 30, 2009, we had $6.4 million in cash and cash equivalents, and $29.9 million invested in marketable securities. The marketable securities primarily consist of $27.1 million invested in U.S. treasury bills and $2.8 million invested in mutual funds. 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 investment choices, however, are conservative and are intended to reduce the risk of loss or any material impact on our financial condition. We are currently reporting an unrealized loss of $544,000 related to the mutual fund as a result of the recent fluctuations in the credit markets impacting the current market value. We consider these unrealized losses temporary as we have the intent and ability to hold these investments long enough to avoid realizing any significant losses.

In fiscal 2010, we plan to continue with our strategic focus on sales growth of *Rochester Medical* brand products, principally in the U.S. and Europe but in other markets as opportunites arise, through increased investment in our sales and marketing programs. We expect such increased investment to be funded primarily through cash generated from current operations. We will also continue to look for other strategic opportunities to increase our product line and distribution capabilities.

In addition to our marketing campaign for our *Magic3* advanced line of silicone intermittent catheters, we will be marketing our new *Strata* brand of Foley catheters. In September 2009, we introduced our new *StrataSI* and *StrataNF* silicone Foley catheters. The improved silicone design consists of a soft, pliable inner core surrounded by ultra-sort, ultra-smooth outer layers allowing for softness and flexibility we believe is unique in an all-silicone catheter. The *StrataNF* version includes a nitrofurazone anti-infective matrix within the silicone.

In September 2009, the *FemSoft Insert* was approved for inclusion in Part IX of the UK Drug Tariff as a prescription product that is reimbursable under the National Healthcare System. In November 2009, Medicare issued a specific reimbursement code which covers our *FemSoft Insert*. We believe the availability of National Healthcare System reimbursement and Medicare reimbursement, both of which commence in 2010, will help this unique device become an economically accessible and often preferred solution for incontinent women in the United Kingdom and in the United States. We are making sales and marketing preparations accordingly to ensure that clinicians and women have access to this excellent choice.

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, consisting of material, labor and manufacturing overhead, are stated at the lower of cost (first-in, first-out method) or market. 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, 2009, this reserve was approximately $126,000, compared to $122,000 at September 30, 2008. If actual future demand or market 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, 2009, this allowance was approximately $63,000 compared to $65,000 at September 30, 2008. If actual future collections or customer liquidity 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 prepayments by certain foreign customers. Receivables generally are due within 30 to 60 days.

Revenue Recognition

We have standard contract terms with all non — Group Purchase Organization customers, which include our independent distributors, of FOB shipping point; as such, sales are recognized upon shipment. GPO customers have terms of FOB destination per the agreement and thus sales are recognized upon delivery of goods to the customer. Revenue is recognized when title and risk of ownership have passed, the price to the buyer is fixed and determinable and recoverability is reasonably assured. For all GPO customer orders shipped within the last five working days of a quarter, we monitor the shipping tracking number for such shipments to verify receipt by the customer. If we are able to verify receipt by the customer by the end of the month, the sale is recognized. Payment terms for all customers range from prepayment to 60 days. Customers cannot return unsold products unless we have authorized such return for warranty claims. We do not grant significant price concessions to our customers.

We warrant that the products we sell to our customers will conform to the description and specifications furnished by us, and that the products will be free from defects in material and workmanship. In the event of a warranty claim, the customer is responsible for shipping the product(s) back to us, freight prepaid. If the failure of the product is due to a breach of warranty, we may repair or replace the defective product(s) at our option and return the repaired or replaced product(s) to the customer, freight prepaid. This is the limit of our warranty liability, and this warranty is made in lieu of all other written or unwritten express or implied warranties. Historically, due to the nature of use of our products and low replacement cost, our warranty exposure has been immaterial.

Other than our limited warranty obligation, we do not have significant post-shipment obligations to, or significant acceptance provisions with, our customers, including our distributors.

During the year ended September 30, 2007, we recognized $525,000 of deferred revenue related to a 10 year distribution agreement with Coloplast. As part of the original agreement, Coloplast paid us $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. 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. During fiscal 2007, both companies mutually agreed to terminate the contract thus accelerating the recognition of our remaining deferred revenue. During fiscal 2008 and 2009, we did not receive upfront license fees under any multiple-element supply and distribution arrangements.

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. For 2009, no valuation allowance has been recorded against the net deferred tax assets because there is sufficient future projected income to sustain that the deferred tax assets will more likely than not be able to be utilized. 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

We follow Accounting Standards Codification (ASC) 350, *Goodwill and Other Intangible* Assets. 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 we have used the market capitalization of our company in our annual impairment test. Goodwill was $4.6 million and $5.2 million as of September 30, 2009 and 2008, respectively. The change is entirely the result of fluctuations in the exchange rate between the British pound and the U.S. dollar.

Finite-life 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 5 to 20 years. All of our intangible assets are finite-life and amortized on a straight-line basis. We review these intangible assets for impairment 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 $6.2 million and $7.1 million as of September 30, 2009 and 2008, respectively.

Long-Lived Assets

We follow ASC 360, *Property, Plant and Equipment.* 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 accounting provisions that are now part of ASC 718, *Compensation-Stock Compensation.* Under the fair value recognition provisions of ASC 718, 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 ASC 718, 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 pro forma disclosures under ASC 718. Total stock-based compensation expense recognized during the fiscal year ended September 30, 2009 was $0.9 million after-tax ($1.3 million pre-tax). See Note 7 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 2009.

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,		
	2009	2008	2007
Total net sales	100.0%	100.0%	100.0%
Cost of sales	51.6	52.5	47.8
Gross margin	48.4	47.5	52.2
Operating expenses:			
Marketing and selling	29.7	27.0	19.9
Research and development	3.6	3.0	2.9
General and administrative	17.3	18.9	20.6
Total operating expenses	50.6	48.9	43.4
Income (loss) from operations	(2.2)	(1.4)	8.8
Other income	3.5	—	119.0
Interest income (expense), net	—	1.9	2.3
Net income before income taxes	1.3%	0.5%	130.1%

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,								
	2009			2008			2007		
	Domestic	International	Total	Domestic	International	Total	Domestic	International	Total
Private label sales:									
Base products	$ 6,756	$ 4,158	$10,914	$ 6,533	$ 3,827	$10,360	$ 7,635	$ 4,200	$11,835
Advanced products	629	—	629	984	—	984	1,042	550	1,592
Total private label sales	7,385	4,158	11,543	7,517	3,827	11,344	8,677	4,750	13,427
Branded sales:									
Base products	4,029	14,605	18,634	3,950	16,493	20,443	3,576	13,586	17,162
Advanced products	3,033	1,589	4,622	2,676	729	3,405	1,678	396	2,074
Total branded sales	7,062	16,194	23,256	6,626	17,222	23,848	5,254	13,982	19,236
Total net sales:	$14,447	$20,352	$34,799	$14,143	$21,049	$35,192	$13,931	$18,732	$32,663

Fiscal Year Ended September 30, 2009 Compared to Fiscal Year Ended September 30, 2008

Net Sales. Net sales decreased 1% to $34.8 million in fiscal 2009 from $35.2 million in the prior fiscal year. The decrease in net sales resulted from a 2% decrease in branded sales for the fiscal year, partially offset by a 2% increase in private label sales. The decrease in branded sales resulted from a decrease in sales of base products in the United Kingdom primarily due to fluctuations in the foreign currency exchange rate between the US dollar and the British pound, partially offset by an increase in sales of advanced products in the U.S. and internationally. The aggregate effect of exchange rate fluctuations for the year resulted in a decrease of $2.8 million in net branded sales. Domestic sales of branded products increased by 7% for fiscal 2009 compared to fiscal 2008. Our international branded sales decreased 6% compared to fiscal 2008 primarily as a result of the change in foreign currency exchange rates. Private label sales of base products were up slightly from the prior year offset by a slight decrease in sales of advanced products to Hollister. Sales of products under the *Rochester Medical* brand comprised 67% of total sales in fiscal 2009, with private label sales representing 33% of total sales. In fiscal 2008, private label sales comprised 32% of total sales. We expect private label sales as a percentage of total sales to decline over time as we focus more on our branded sales.

Gross Margin. Our gross margin as a percentage of net sales was 48% in fiscal 2009 compared to 47% in the prior fiscal year. Our increase in gross margin in fiscal 2009 was primarily affected by increased sales of higher margin products and lower raw material costs.

Marketing and Selling. For fiscal 2009, we increased the investment in our sales and marketing programs, primarily through cash generated from current operations, to support *Rochester Medical* branded sales growth in the U.S. and Europe. 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 9% in fiscal 2009 as compared to fiscal 2008, with marketing and selling expense of approximately $10.3 million in fiscal 2009 and $9.5 million in fiscal 2008. The increase in marketing and selling expense is primarily related to $660,000 of increased advertising and project costs, $63,000 of compensation expenses, $54,000 increase in consulting fees, $34,000 in utilities and $33,000 of increased travel expenses. Marketing and selling expense as a percentage of net sales for fiscal 2009 was 30% compared to 27% for fiscal 2008.

Research and Development. Research and development expense primarily includes internal labor costs, materials used to develop new products 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 19% to $1,241,000 in fiscal 2009 from $1,044,000 in the prior fiscal year. The increase in research and development expense relates primarily to increased compensation expense of $177,000 and $50,000 of project costs, offset by a decrease in supplies expense of $30,000. Research and development expense as a percentage of net sales for fiscal 2009 and fiscal 2008 was 4% and 3%, respectively.

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 declined to $6.0 million in 2009 from $6.7 million in fiscal 2008. The changes in general and administrative expense primarily relate to decreased administrative costs of $286,000 in professional fees, $211,000 of other expenses, $82,000 of travel expenses, $63,000 of utilities expenses, $44,000 of consulting fees and $38,000 in charitable contributions, offset by increases of $91,000 in compensation expense. General and administrative expense as a percentage of net sales for fiscal 2009 and fiscal 2008 was 17% and 19%, respectively.

Interest Income. Interest income decreased 77% to $283,000 in fiscal 2009 from $1.2 million in the prior fiscal year. The decrease reflects overall lower interest rates on investments.

Interest Expense. Interest expense decreased 46% to $259,000 in fiscal 2009 from $478,000 in fiscal 2008. The decrease in interest expense reflects decreases in outstanding debt used to partially finance our asset acquisitions in June 2006 from Mentor and Coloplast and refinancing of debt at a lower interest rate.

Income Taxes. As of September 30, 2009, we have federal net operating loss carryforwards available to offset future taxable income. No valuation allowance has been recorded against the net deferred tax assets because there is sufficient future projected income to sustain that the deferred tax assets will more likely than not be able to be utilized.

For fiscal 2009, we had an effective tax rate of approximately 77% that was affected by foreign operations, incentive stock options and research and development tax credits. The amount of these items in comparison to our net income for the current year results in a significant effect on the effective tax rate percentage. In future periods of taxable earnings, we expect to report an income tax provision using an effective tax rate in the range of 30-34%.

Net Income. Our net income decreased to $109,000 in fiscal 2009 from $759,000 in 2008. Net income was impacted by our increased strategic investment in sales and marketing programs and increased costs in research and development of new products. Additionally, we experienced a challenging economic environment in fiscal 2009 in which some customers in geographic regions in which we operate reduced or deferred purchases of our products.

Fiscal Year Ended September 30, 2008 Compared to Fiscal Year Ended September 30, 2007

Net Sales. Net sales increased 7.7% to $35.2 million in fiscal 2008 from $32.7 million in the prior fiscal year. The increase in net sales was a result of an increase in branded sales offset by a decrease in private label sales. The increase in branded sales primarily was attributable to increased sales of branded advanced products in the United States and increased sales of branded base products in the United Kingdom. Domestic sales of branded products increased by 26% for fiscal 2008 compared to fiscal 2007. Our international branded sales increased 23% compared to fiscal 2007. Private label sales of both base products and advanced products were down from last year, primarily as a result of decreased sales to Coloplast and Hollister. Sales of products under the *Rochester Medical* brand comprised 68% of total sales in fiscal 2008, with private label sales representing 32% of total sales. In fiscal 2007, private label sales comprised 41% of total sales.

Gross Margin. Our gross margin as a percentage of net sales was 47% in fiscal 2008 compared to 52% in the prior fiscal year. Our decrease in gross margin in fiscal 2008 was primarily impacted by increased costs for medical insurance, raw materials and freight during 2008. Additionally, a significant portion of our increased sales were of lower margin products.

Marketing and Selling. For fiscal 2008, we increased the investment in our sales and marketing programs, primarily through cash generated from current operations, to support *Rochester Medical* branded sales growth in the U.S. and Europe. 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 46% in fiscal 2008 as compared to fiscal 2007, with marketing and selling expense of approximately $9.5 million in fiscal 2008 and $6.5 million in fiscal 2007. The increase in marketing and selling expense is primarily related to increased sales personnel and related expenses of $660,000 incurred in the Company's U.K. operations, $1.6 million in increased staff in U.S. acute care marketing, $550,000 of increased advertising and

project costs and $140,000 of increased stock-based compensation expense. Marketing and selling expense as a percentage of net sales for fiscal 2008 was 27% compared to 20% for fiscal 2007.

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 11% to $1,044,000 in fiscal 2008 from $943,000 in the prior fiscal year. The increase in research and development expense relates primarily to increased project costs of $168,000 and $15,000 of increased stock-based compensation expense, offset by a decrease in compensation expense of $103,000. Research and development expense as a percentage of net sales for each of fiscal 2008 and fiscal 2007 was 3%.

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 remained flat at $6.7 million in fiscal 2008 and fiscal 2007. The changes in general and administrative expense primarily relate to decreased administrative costs of $900,000 of stock-based compensation expense, offset by increases of $610,000 in professional fees, $55,000 of insurance, $50,000 of compensation expense, $60,000 in charitable contributions and $40,000 related to travel. General and administrative expense as a percentage of net sales for fiscal 2008 and fiscal 2007 was 19% and 21%, respectively.

Interest Income. Interest income decreased 4% to $1.2 million in fiscal 2008 from $1.3 million in the prior fiscal year. The decrease reflects overall lower interest rates on investments.

Interest Expense. Interest expense decreased 7% to $478,000 in fiscal 2008 from $513,000 in fiscal 2007. The decrease in interest expense reflects decreases in outstanding debt used to partially finance our asset acquisitions in June 2006 from Mentor and Coloplast.

Income Taxes. For the year ended September 30, 2008, we had a federal net operating loss. No valuation allowance was recorded against the net deferred tax assets because there was sufficient future projected income as well as excess income from 2007 to sustain that the deferred tax assets will more likely than not be able to be utilized.

As of September 30, 2008, we had 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. For fiscal 2008, we had an effective income tax rate of approximately (320)% due to a few new or one time items. We had a one time adjustment for deferred taxes resulting from a change in tax rate as well as retroactive changes. There was also a first time deduction for Domestic Production Activities, arising from the change in taxable income position in the 2007 fiscal year. Lastly, we performed a detailed analysis of our research and development activities for the current and prior years which, coupled with the change in taxable income position in the 2007 fiscal year, resulted in additional tax credits. Other items having a material effect on the effective income tax rate were tax exempt interest and unrecognized tax benefits.

Net Income. Our net income decreased to $759,000 in fiscal 2008, which is more consistent with our expectations compared to $34,050,000 in fiscal 2007. Lawsuit settlements of approximately $39 million pre-tax were recognized in fiscal 2007. Net income was also impacted by our increased strategic investment in sales and marketing programs.

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 $36.3 million at September 30, 2009 compared with $37.0 million at September 30, 2008. The decrease in cash primarily resulted from cash used for capital expenditures and debt repayments offset by cash provided by litigation settlements, stock option exercises and operations. As of September 30, 2009, we had $29.9 million invested in marketable securities. The marketable securities primarily consist of $27.1 million invested in U.S. treasury bills and $2.8 million invested in mutual

funds. 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 investment choices, however, are conservative and are intended to reduce the risk of loss or any material impact on our financial condition. We are currently reporting an unrealized loss of $544,000 related to the mutual fund as a result of the recent fluctuations in the credit markets impacting the current market value. We consider these unrealized losses temporary as we have the intent and ability to hold these investments long enough to avoid realizing any significant losses.

We generated a net $1.7 million of cash in operating activities during the year compared with $2.4 million for the same period last year, with the primary difference being increased levels of inventory in 2009. Cash flow provided by operating activities in 2009 was comprised of net income of $109,000, decreased by an increase in net working capital components and increased by net non-cash charges of $3.2 million, including depreciation and amortization of $1.9 million and stock-based compensation of $1.3 million. Significant working capital changes are as follows:

- a $658,000 increase in accounts receivable reflecting increasing sales activity over prior year;
- a $1,102,000 increase in inventory as we increased our finished goods and work-in-process inventory to support the increase in sales volume;
- a $197,000 decrease in deferred income taxes;
- a $321,000 decrease in accounts payable reflecting timing of payments; and
- a $325,000 increase in other current liabilities including normal business expense accruals.

During fiscal 2009, our working capital position, excluding cash and marketable securities, increased by $519,000. Accounts receivable balances increased $658,000 during the fiscal year primarily due to increased sales at the end of the fourth quarter. Inventories as of September 30, 2009 increased $1.1 million over fiscal 2008 as we carried more inventory in anticipation of increased sales and new product launches. Other current assets were relatively flat with fiscal 2008. 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 $2.7 million in fiscal 2009.

Financing activities, primarily long term debt payments and share repurchases offset by increases in short term debt and proceeds from stock option exercises, used net cash of $653,000 in fiscal 2009.

In June 2006, we entered into a $7,000,000 credit facility with U.S. Bank National Association. The credit facility consisted of a $5,000,000 term loan payable in five years and accruing interest at a rate equal to 4.77%, and a revolving line of credit of up to $2,000,000, maturing annually on March 31, with interest payable monthly at a floating rate based on the quoted one-month LIBOR rate plus 1.60%. In March 2009, we paid off the entire term loan and terminated the revolving line of credit.

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 imputed interest on the note at 6.90% and reflect a net liability of $1,927,910 on our balance sheet as of September 30, 2009.

In February 2009, we entered into a $14,000,000 credit facility with UBS Financial. The credit facility consists of a revolving line of credit of up to $14,000,000 with interest accruing monthly at a floating rate based on the quoted one-month LIBOR rate plus 1.25%. As of September 30, 2009, we had an outstanding balance of $1,878,447 under the revolving line of credit. Our obligations under the credit facility are payable on demand and are secured by our investments in marketable securities held at UBS.

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. Our ability to obtain financing for acquisitions or other general corporate and commercial purposes will depend on our operating and financial performance and is also subject to prevailing economic conditions and to financial, business and other factors beyond our control. Recently, global credit markets and the financial services industry have been experiencing a period of unprecedented turmoil characterized by the bankruptcy, failure or sale of various financial institutions, a general tightening of credit, and an unprecedented level of market intervention from the United States and other governments. These events have adversely affected the U.S. and world economy, and may adversely affect the availability and cost of financing. 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, 2009:

	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 . .	$3,852,794	$2,833,059	$1,019,735	$—	$—
Unrecognized tax benefits under ASC 740[1]	55,889	—	55,889	—	—
Operating leases	581,429	252,458	328,971		
Purchase obligations (general operating)	2,044,707	2,044,707	—	—	—
Total Contractual Obligations . . .	$6,534,819	$5,130,224	$1,404,595	$—	$—

(1) See Item 8 of Part II of this Form 10-K, "Financial Statements and Supplementary Data — Note 8 — Income Taxes."

Off-Balance Sheet Arrangements

As of September 30, 2009, 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 June 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement No 162* (the Codification). The Codification reorganized the existing U.S. accounting and reporting standards into a single source of authoritative accounting principles arranged by topic. The Codification supersedes all existing U.S. accounting standards; all other accounting literature not included in the Codification, except for rules and interpretive releases of the SEC, which are also sources of authoritative U.S. GAAP for SEC registrants, is considered non-authoritative. The Codification was effective on a prospective basis for interim and annual reporting periods ending after September 15, 2009. We adopted the Codification in our year ended September 30, 2009. The adoption of the

Codification changed our references to U.S. GAAP, but it had no impact on our consolidated financial position or results of operations.

In September 2006, the FASB issued new guidance for using fair value to measure assets and liabilities. The new guidance, which is now a part of ASC 820, *Fair Value Measurements and Disclosures*, defines fair value, establishes a framework for measuring fair value under U.S. GAAP and expands disclosures about fair value measurements. The new guidance applies whenever other pronouncements require or permit assets or liabilities to be measured by fair value and while not requiring new fair value measurements, may change current practices. We adopted the new guidance in the second quarter of fiscal 2009. The adoption did not have a material impact on our consolidated financial position or results of operations, as it is a disclosure-only standard.

In December 2007, the FASB issued updated accounting standards on business combinations. The new standards, which are now part of ASC 805, *Business Combinations*, establish principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. ASC 805 also provides guidance for recognizing and measuring the goodwill acquired in the business combination or a gain from a bargain purchase and determines what information to disclose to enable users of financial statements to evaluate the nature and financial effects of the business combination. ASC 805 applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which for us is the first quarter of fiscal 2010. ASC 805 will impact our consolidated financial statements for business combinations with an acquisition date on or after adoption in the first quarter of fiscal 2010.

In December 2007, the FASB issued new accounting and reporting standards for noncontrolling interests in a subsidiary and for the deconsolidation of a subsidiary. Under the new standards, which are now part of ASC 810, *Noncontrolling Interests in Consolidated Financial Statement*, minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. ASC 810 also establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary and requires expanded disclosures. The new standards are effective for fiscal years beginning on or after December 15, 2008. We do not expect the adoption of ASC 810 will have a material impact on our financial position or results of operations.

In March 2008, the FASB issued new guidance on the disclosure of derivative instruments and hedging activities. The new guidance, which is now a part of ASC 815, *Derivatives and Hedging Activities*, requires enhanced disclosures about an entity's derivative and hedging activities in order to improve the transparency of financial reporting. The provisions of the new guidance were effective for fiscal years and interim periods beginning after November 15, 2008. We adopted the new guidance in the first quarter of 2009. The adoption did not have a material impact on our consolidated financial position or results of operations, as it is a disclosure-only standard.

In April 2009, the FASB issued new guidance related to the disclosure of the fair value of financial instruments. The new guidance, which is now a part of ASC 825, *Financial Instruments*, requires fair value disclosures in both interim as well as annual financial statements in order to provide more timely information about the effects of current market conditions on financial instruments. The new guidance is effective for interim and annual periods ending after June 15, 2009. We adopted the new guidance for our interim period ending June 30, 2009. The adoption did not have a material impact on our consolidated financial position for results of operations, as it is a disclosure-only standard.

In April 2009, the FASB issued new guidance applicable to investments in debt securities for which other-than-temporary impairments may be recorded. Under the new guidance, which is now a part of ASC 320, *Investments — Debt and Equity Securities,* if an entity's management asserts that it does not have the intent to sell a debt security and it is more likely than not that it will not have to sell the security before recovery of its cost basis, then an entity may separate other-than-temporary impairments into two components: 1) the amount related to credit losses (recorded in earnings), and 2) all other amounts (recorded in other comprehensive income). This guidance is to be applied prospectively and is effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption did not have a material impact on our consolidated financial position or results of operations.

In May 2009, the FASB issued new guidance for accounting for subsequent events. The new guidance, which is now a part of ASC 855, *Subsequent Events,* establishes the accounting for, and disclosure of, events that occur after

the balance sheet date but before financial statements are issued or are available to be issued. The new guidance requires the disclosure of the date through which and entity has evaluated subsequent events and the basis for that date. We adopted the new guidance for our interim period ending June, 30, 2009. The adoption of the new guidance and the related disclosures had no impact on our consolidated financial position or results of operations.

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 establishing our separate *Rochester Medical* brand identity;
- the uncertainty of successfully integrating and growing our U.K. operations;
- the risks associated with operating an international business, including the impact of foreign currency exchange rate fluctuations;
- 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;
- the impact of continued healthcare cost containment;
- new laws related to healthcare availability, healthcare reform, payment for healthcare products and services or the marketing and distribution of products, including legislative or administrative reforms to the U.S. Medicare and Medicaid systems or other U.S. or international reimbursement systems;
- changes in the tax or environmental laws or standards affecting our business;
- 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, 2009. 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, 2009.

Our independent auditor has audited our consolidated financial statements and the effectiveness of internal controls over financial reporting as of September 30, 2009 as stated in their reports on pages 38 and 39.

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 U.S. 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 investment choices, however, are conservative in light of current economic conditions, and include primarily U.S. treasury bills to reduce the risk of loss or any material impact on our financial condition. Our revolving line of credit bears interest at a floating rate based on the quoted one-month LIBOR rate plus 1.25%. As of September 30, 2009 we had an outstanding balance of $1,878,447 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-U.S. currency transactions. Sales through our subsidiary, Rochester Medical Limited, 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, 2009, 2008 and 2007

	Page
Reports of Independent Registered Public Accounting Firms	38-40
Audited Financial Statements	
Consolidated Balance Sheets	41
Consolidated Statements of Operations	42
Consolidated Statement of Shareholders' Equity and Comprehensive Income (Loss)	43
Consolidated Statements of Cash Flows	44
Notes to Consolidated Financial Statements	45

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Rochester Medical Corporation

We have audited the accompanying consolidated balance sheet of Rochester Medical Corporation (a Minnesota corporation) and subsidiary (collectively, the "Company") as of September 30, 2009 and 2008 and the related consolidated statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the two years in the period ended September 30, 2009. Our audit of the basic financial statements included the financial statement schedule listed in the index appearing under Item 15. 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 and financial schedule 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 provides 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, 2009 and 2008, and the results of their operations and their cash flows for each of the two years in the period ended September 30, 2009 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Rochester Medical Corporation's internal control over financial reporting as of September 30, 2009, 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 11, 2009 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ GRANT THORNTON LLP

Minneapolis, Minnesota
December 11, 2009

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Rochester Medical Corporation

We have audited Rochester Medical Corporation's (the "Company") internal control over financial reporting as of September 30, 2009, based on criteria established in *Internal Control — Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). The Company'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 included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on 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, Rochester Medical Corporation maintained, in all material respects, effective internal control over financial reporting as of September 30, 2009, based on criteria established in *Internal Control — Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Rochester Medical Corporation as of September 30, 2009 and 2008, and the related consolidated statements of operations, shareholders' equity and comprehensive income (loss), and cash flows and financial statement schedule for each of the two years in the period ended September 30, 2009, and our report dated December 11, 2009 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
December 11, 2009

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
of Rochester Medical Corporation

We have audited the consolidated statements of operations, shareholders' equity and comprehensive income, and cash flows of Rochester Medical Corporation and subsidiary for the year ended September 30, 2007. Our audit also included the financial statement schedule of Rochester Medical Corporation listed in Item 15(a)(2). 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 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the results of Rochester Medical Corporation and subsidiary's operations and their cash flows for the year 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.

/s/ McGladrey & Pullen LLP

Minneapolis, Minnesota
December 3, 2007

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS

	September 30, 2009	September 30, 2008
Assets:		
Current assets:		
Cash and cash equivalents	$ 6,365,584	$ 8,508,000
Marketable securities	29,896,740	28,493,648
Accounts receivable, less allowance for doubtful accounts ($63,369 — 2009; $65,202 — 2008)	6,418,656	6,009,023
Inventories, net	9,710,234	8,745,873
Prepaid expenses and other current assets	1,076,183	1,110,291
Deferred income tax asset	1,153,964	1,143,931
Total current assets	54,621,361	54,010,766
Property, plant and equipment:		
Land	702,120	739,836
Buildings	7,145,768	6,956,240
Equipment and fixtures	16,954,719	16,086,643
	24,802,607	23,782,719
Less accumulated depreciation	(15,118,799)	(13,899,390)
Total property, plant and equipment	9,683,808	9,883,329
Deferred income tax asset	768,874	831,299
Goodwill	4,648,165	5,169,661
Finite life intangibles, less accumulated amortization ($2,120,096 — 2009; $1,511,307 — 2008)	6,017,944	6,860,213
Patents, less accumulated amortization ($1,207,316 — 2009; $1,147,088 — 2008)	224,815	227,358
Total assets	$ 75,964,967	$ 76,982,626
Liabilities and Shareholders' Equity:		
Current liabilities:		
Accounts payable	$ 1,755,472	$ 2,127,470
Accrued compensation	1,176,949	915,661
Accrued expenses	350,403	254,993
Current maturities of debt	2,786,622	1,940,292
Total current liabilities	6,069,446	5,238,416
Long-term liabilities:		
Other long term liabilities	55,889	239,496
Long-term debt, less current maturities	1,019,735	3,806,185
Total long-term liabilities	1,075,624	4,045,681
Shareholders' equity:		
Common stock, no par value:		
Authorized shares — 40,000,000		
Issued and outstanding shares: (12,190,367 — 2009; 11,936,586 — 2008)	56,840,856	54,223,669
Retained earnings	14,832,213	14,723,541
Accumulated other comprehensive loss	(2,853,172)	(1,248,681)
Total shareholders' equity	68,819,897	67,698,529
Total liabilities and shareholders' equity	$ 75,964,967	$ 76,982,626

The accompanying notes are an integral part of these financial statements.

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Fiscal Years Ended September 30,		
	2009	2008	2007
Net sales	$34,798,829	$35,191,949	$32,663,087
Cost of sales	17,973,314	18,483,985	15,619,178
Gross profit	16,825,515	16,707,964	17,043,909
Operating expenses:			
Marketing and selling	10,327,396	9,498,596	6,490,497
Research and development	1,241,095	1,044,205	943,225
General and administrative	6,006,906	6,658,002	6,742,665
Total operating expenses	17,575,397	17,200,803	14,176,387
Income (loss) from operations	(749,882)	(492,839)	2,867,522
Other income (expense):			
Interest income	283,195	1,239,689	1,288,603
Other income (expense)	1,200,442	(88,642)	38,855,000
Interest expense	(259,341)	(477,560)	(513,296)
	1,224,296	673,487	39,630,307
Net income before income taxes	474,414	180,648	42,497,829
Income tax benefit (expense)	(365,742)	578,455	(8,447,649)
Net income	$ 108,672	$ 759,103	$34,050,180
Net income per common share — basic	$ .01	$ .06	$ 2.97
Net income per common share — diluted	$ .01	$ .06	$ 2.77
Weighted average number of common shares outstanding — basic	12,045,313	11,815,904	11,449,646
Weighted average number of common shares outstanding — diluted	12,639,853	12,577,337	12,272,172

The accompanying notes are an integral part of these financial statements.

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

	Common Stock		Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total
	Shares	Amount			
Balance at September 30, 2006	11,086,560	$43,128,727	$(20,085,742)	$ 53,577	$23,096,562
Comprehensive income (loss):					
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
Tax benefit of stock options exercised	—	2,325,866	—	—	2,325,866
Stock based compensation	—	2,117,011	—	—	2,117,011
Stock option exercises	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
Comprehensive income (loss):					
Net income for the year	—	—	759,103	—	759,103
Foreign currency translation adjustment	—	—	—	(1,456,869)	(1,456,869)
Tax effect on unrealized loss on securities	—	—	—	138,890	138,890
Unrealized loss on available-for-sale securities	—	—	—	(324,450)	(324,450)
Subtotal — comprehensive loss					(883,326)
Tax benefit of stock options exercised	—	1,364,491	—	—	1,364,491
Stock based compensation	—	1,364,561	—	—	1,364,561
Stock option exercises	245,700	1,343,878	—	—	1,343,878
Balance at September 30, 2008	11,936,586	54,223,669	14,723,541	(1,248,681)	67,698,529
Comprehensive income(loss):					
Net income for the year	—	—	108,672	—	108,672
Foreign currency translation adjustment	—	—	—	(1,624,527)	(1,624,527)
Tax effect on unrealized loss on securities	—	—	—	142,587	142,587
Unrealized loss on available-for-sale securities	—	—	—	(122,551)	(122,551)
Subtotal — comprehensive loss					(1,495,819)
Tax benefit of stock options exercised	—	562,308	—	—	562,308
Stock based compensation	—	1,330,220	—	—	1,330,220
Common stock repurchased	(110,653)	(1,058,041)	—	—	(1,058,041)
Stock option exercises	364,434	1,782,700	—	—	1,782,700
Balance at September 30, 2009	12,190,367	$56,840,856	$ 14,832,213	$(2,853,172)	$68,819,897

The accompanying notes are an integral part of these financial statements.

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Fiscal Years Ended September 30,		
	2009	2008	2007
Operating Activities:			
Net income	$ 108,672	$ 759,103	$ 34,050,180
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation	1,234,081	1,209,554	1,161,291
Amortization	692,756	717,009	724,067
Stock based compensation	1,330,220	1,364,561	2,117,011
Deferred revenue	—	—	(564,286)
Deferred income taxes	196,545	(528,535)	(203,070)
Tax benefit of stock options exercised	—	404,959	2,325,866
Changes in operating assets and liabilities, net of the effects of business acquisition:			
Accounts receivable	(657,793)	(841,382)	(877,450)
Inventories	(1,101,735)	(604,318)	(2,966,577)
Prepaid expenses and other current assets	(62,859)	(655,116)	(240,402)
Accounts payable	(320,632)	1,096,684	(197,366)
Income tax payable	(60,034)	(415,671)	500,688
Other current liabilities	325,055	(110,327)	(308,524)
Net cash provided by operating activities	1,684,276	2,396,521	35,521,428
Investing Activities:			
Purchases of property, plant and equipment	(1,171,788)	(1,609,741)	(2,482,625)
Business acquisition	—	—	60,579
Patents	(57,685)	(26,915)	(49,795)
Purchase of marketable securities	(55,358,876)	(76,658,063)	(36,557,555)
Proceeds from sales and maturities of marketable securities	53,853,269	78,444,303	5,975,000
Net cash provided by (used in) investing activities	(2,735,080)	149,584	(33,054,396)
Financing Activities:			
Payments on capital leases	—	—	(64,030)
Increase in short-term debt	2,000,000	—	—
Payments on long-term debt	(3,940,120)	(2,169,233)	(1,744,919)
Repurchase of common stock	(1,058,041)	—	—
Excess tax benefit from exercises of stock options	562,308	959,523	—
Net proceeds from issuance of common stock from option exercises	1,782,700	1,343,877	2,579,135
Net cash provided by (used in) financing activities	(653,153)	134,167	770,186
Effect of exchange rate on cash and cash equivalents	(438,459)	(843,628)	527,440
Increase (decrease) in cash and cash equivalents	(2,142,416)	1,836,644	3,764,658
Cash and cash equivalents at beginning of year	8,508,000	6,671,356	2,906,698
Cash and cash equivalents at end of year	$ 6,365,584	$ 8,508,000	$ 6,671,356
Supplemental Cash Flow Information:			
Cash paid for interest	$ 443,791	$ 476,577	$ 604,635
Cash paid for income taxes	313,640	785,000	5,750,000

The accompanying notes are an integral part of these financial statements.

1. Description of Business and Basis of Presentation

Rochester Medical Corporation 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*, *StrataNF* 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 Company's fiscal year end is September 30. The accompanying financial statements include the accounts of Rochester Medical Corporation and Rochester Medical Limited, its wholly owned subsidiary in the United Kingdom, together which are herein referred to as "the Company".

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 and accounts receivable, fair value assumptions related to investments, deferred income tax assets and stock-based compensation. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Rochester Medical Corporation 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. Cash and cash equivalents includes balances in foreign accounts totaling $4.2 million and $3.9 million at September 30, 2009 and 2008, respectively. 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

As of September 30, 2009, the Company has $29.9 million invested in high quality, investment grade debt securities, primarily consisting of $27.1 million invested in U.S. treasury bills and $2.8 million invested in a mutual fund. The Company is currently reporting an unrealized loss of $544,268 related to the mutual fund as a result of the recent fluctuations in the credit markets impacting the current market value. The Company considers these unrealized losses temporary as it has the intent and ability to hold these investments to maturity.

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. The cost and fair value of available-for-sale securities were as follows:

	Cost	Unrealized Loss	Fair Value
September 30, 2009	$30,441,008	$(544,268)	$29,896,740
September 30, 2008	$28,915,366	$(421,718)	$28,493,648

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

Effective October 1, 2008, the Company adopted the accounting standards which are now part of Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures*, for financial assets and liabilities that are re-measured and reported at fair value at each reporting period. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 requires that fair value measurements be classified and disclosed using one of the following three categories:

Level 1. Quoted prices (unadjusted) in active markets for identical assets or liabilities;

Level 2. Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities; quoted prices for identical or similar assets in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3. Inputs that are unobservable for the asset or liability and that are significant to the fair value of the assets or liabilities.

The adoption of these standards did not have a material impact on the Company's consolidated financial statements. The Company has determined that the values given to its marketable securities are appropriate and are measured using Level 1 inputs.

Fair Value of Financial Instruments

The carrying amounts of all financial instruments, including cash, accounts receivable, accounts 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 rates offered to the Company for debt.

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 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. Accounts outstanding longer than the contractual payment terms are considered past due. The Company determines its allowances by considering a number of factors, including the length of time accounts receivables are past due, the Company's previous loss history, the customer's current ability to pay its obligation to the Company, and the condition of the general economy and the industry as a whole. The Company writes off accounts receivable when they become uncollectible, and payments subsequently received on such receivables are credited to the allowance for doubtful accounts. Accounts receivable balances written off have been within management's expectations.

Inventories

Inventories, consisting of material, labor and manufacturing overhead, are stated at the lower of cost (first-in, first-out method) or market.

Property, Plant and Equipment

Property, plant 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 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, 2009, 2008 and 2007.

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 ASC 350, *Goodwill and Other Intangible Assets*. Under ASC 350, goodwill and intangibles with indefinite useful lives are not amortized. ASC 350 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. The Company tests annually for impairment on the anniversary date of the acquisition of the asset, which is currently on June 2nd of each fiscal year, or more frequently if events and circumstances indicate that the asset might be impaired. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated undiscounted future cash flows, an impairment charge would be recognized by the amount that the carrying amount of the asset exceeds the fair value of the asset. The Company performed annual goodwill impairment testing by comparing the market value of the Company's assets at June 2, 2009 to the net book value of its equity, and concluded that the goodwill was not impaired. No impairment loss was recognized in the fiscal years ended September 30, 2009, 2008 and 2007. The decrease in value of goodwill as of September 30, 2009 is entirely related to the change in foreign currency exchange rates in the United Kingdom.

Long-Lived Assets

The Company reviews its long-lived assets for impairment as prescribed by ASC 360, *Property, Plant, and Equipment,* whenever events or changes in circumstances indicate that its 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. No impairment loss was recognized in the fiscal years ended September 30, 2009, 2008 and 2007.

Foreign Currency Translation

The financial statements of the Company's non-U.S. subsidiary are translated into U.S. dollars in accordance with ASC 830, *Foreign Currency Matters*. Under ASC 830, 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).

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.

Revenue Recognition

The Company has standard contract terms with all non-Group Purchase Organization customers, which include our independent distributors, of FOB shipping point; as such, sales are recognized upon shipment. Group Purchase Organization customers have terms of FOB destination per the agreement and thus sales are recognized upon delivery of goods to the customer. Revenue is recognized when title and risk of ownership have passed, the price to the buyer is fixed and determinable and recoverability is reasonably assured. For all Group Purchase Organization customer orders shipped within the last five working days of a quarter, the Company monitors the shipping tracking number for such shipments to verify receipt by the customer. If the Company is able to verify receipt by the customer by the end of the month, the sale is recognized. Payment terms for all customers range from prepayment to 60 days. Customers cannot return unsold products unless the Company has authorized such return for warranty claims. The Company does not grant significant price concessions to its customers.

The Company warrants that the products it sells to its customers will conform to the description and specifications furnished by the Company, and that the products will be free from defects in material and workmanship. In the event of a warranty claim, the customer is responsible for shipping the product(s) back to the Company, freight prepaid. If the failure of the product is due to a breach of warranty, the Company may repair or replace the defective product(s) at its option and return the repaired or replaced product(s) to the customer, freight prepaid. This is the limit of the Company's warranty liability, and this warranty is made in lieu of all other written or unwritten express or implied warranties. Historically, due to the nature of use of the Company's products and low replacement cost, the Company's warranty exposure has been immaterial.

Other than the Company's limited warranty obligation, the Company does not have significant post-shipment obligations to, or significant acceptance provisions with, its customers, including its distributors.

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. 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 on-going services or performance by the Company. During fiscal 2007, both companies mutually agreed to terminate the contract thus accelerating the recognition of the remaining deferred revenue of the Company. During fiscal 2008 and 2009, the Company did not receive upfront license fees under any multiple-element supply and distribution arrangements.

Shipping and Handling

Shipping and handling billed to customers is recorded as revenue. Shipping and handling costs are recorded within cost of goods sold.

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.

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. The Company has determined it is more likely than not that all deferred tax assets will be realized and therefore no valuation allowance is necessary.

It is the Company's practice to recognize penalties and/or interest to income tax matters in income tax expenses. As of September 30, 2009, the Company did not have a material amount of accrued interest or penalties related to unrecognized tax benefits.

The Company is subject to income tax examinations in the U.S. federal jurisdiction, as well as in the United Kingdom and various state jurisdictions. The Internal Revenue Service ("IRS") completed an examination of the Company's income tax return for the fiscal year ended September 30, 2007 and a settlement was reached in September 2009. Reserves in accordance with ASC 740, *Income Taxes* for unrecognized tax benefits was more than the additional taxes assessed by the IRS. The remaining reserves relating to the 2007 tax year were released during the year ended September 30, 2009, as a result of the settlement.

Advertising Costs

The Company incurred advertising expenses of approximately $929,000, $946,000 and $397,000 for the years ended September 30, 2009, 2008 and 2007, respectively. All advertising costs are charged to operations as incurred.

Stock-Based Compensation

Stock-based compensation expense 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 accounting provisions that are now part of ASC 718, *Compensation-Stock 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 ASC 718, recognized utilizing the accelerated expense attribution method for awards with graded vesting. The Company recorded approximately $1,330,000, $1,365,000 and $2,100,000 ($878,000, $887,000 and $1,365,000 net of tax) of related stock-based compensation expense for the years ended September 30, 2009, 2008 and 2007, respectively.

Net Income Per Share

Net income per common share is calculated in accordance with ASC 260, *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,		
	2009	2008	2007
Numerator:			
Net income	$ 108,672	$ 759,103	$34,050,180
Denominator:			
Denominator for basic net income per common share — weighted average shares outstanding	12,045,313	11,815,904	11,449,646
Effect of dilutive stock options	594,540	761,433	822,526
Denominator for diluted net income per common share — weighted average shares outstanding	12,639,853	12,577,337	12,272,172

Employee stock options of 230,000, 5,000 and 30,000 for fiscal years 2009, 2008 and 2007, 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 June 2009, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles — a replacement of FASB Statement No 162* (the Codification). The Codification reorganized the existing U.S. accounting and reporting standards into a single source of authoritative accounting principles arranged by topic. The Codification supersedes all existing U.S. accounting standards; all other accounting literature not included in the Codification, except for rules and interpretive releases of the SEC, which are also sources of authoritative U.S. GAAP for SEC registrants, is considered non-authoritative. The Codification was effective on a prospective basis for interim and annual reporting periods ending after September 15, 2009. The Company adopted the Codification in its fiscal year ended September 30, 2009. The adoption of the Codification changed the Company's references to U.S. GAAP, but it had no impact on the Company's consolidated financial position or results of operations.

In September 2006, the FASB issued new guidance for using fair value to measure assets and liabilities. The new guidance, which is now a part of ASC 820, *Fair Value Measurements and Disclosures*, defines fair value, establishes a framework for measuring fair value under U.S. GAAP and expands disclosures about fair value measurements. The new guidance applies whenever other pronouncements require or permit assets or liabilities to be measured by fair value and while not requiring new fair value measurements, may change current practices. The Company adopted the new guidance in the second quarter of fiscal 2009. The adoption did not have a material impact on the Company's consolidated financial position or results of operations, as it is a disclosure-only standard.

In December 2007, the FASB issued updated accounting standards on business combinations. The new standards, which are now part of ASC 805, *Business Combinations*, establish principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. ASC 805 also provides guidance for recognizing and measuring the goodwill acquired in the business combination or a gain from a bargain purchase and determines what information to disclose to enable users of financial statements to evaluate the nature and financial effects of the business combination. ASC 805 applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, which for the Company is the first quarter of fiscal 2010. ASC 805 will impact the Company's consolidated financial statements for business combinations with an acquisition date on or after adoption in the first quarter of fiscal 2010.

In December 2007, the FASB issued new accounting and reporting standards for noncontrolling interests in a subsidiary and for the deconsolidation of a subsidiary. Under the new standards, which are now part of ASC 810, *Noncontrolling Interests in Consolidated Financial Statement*, minority interests will be recharacterized as noncontrolling interests and classified as a component of equity. ASC 810 also establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary and requires expanded disclosures. The new standards are effective for fiscal years beginning on or after December 15, 2008. The Company does not expect the adoption of ASC 810 will have a material impact on its financial position or results of operations.

In March 2008, the FASB issued new guidance on the disclosure of derivative instruments and hedging activities. The new guidance, which is now a part of ASC 815, *Derivatives and Hedging Activities*, requires enhanced disclosures about an entity's derivative and hedging activities in order to improve the transparency of

financial reporting. The provisions of the new guidance were effective for fiscal years and interim periods beginning after November 15, 2008. The Company adopted the new guidance in the first quarter of 2009. The adoption did not have a material impact on the Company's consolidated financial position or results of operations, as it is a disclosure-only standard.

In April 2009, the FASB issued new guidance related to the disclosure of the fair value of financial instruments. The new guidance, which is now a part of ASC 825, *Financial Instruments*, requires fair value disclosures in both interim as well as annual financial statements in order to provide more timely information about the effects of current market conditions on financial instruments. The new guidance is effective for interim and annual periods ending after June 15, 2009. The Company adopted the new guidance for its interim period ending June 30, 2009. The adoption did not have a material impact on the Company's consolidated financial position for results of operations, as it is a disclosure-only standard.

In April 2009, the FASB issued new guidance applicable to investments in debt securities for which other-than-temporary impairments may be recorded. Under the new guidance, which is now a part of ASC 320, *Investments — Debt and Equity Securities,* if an entity's management asserts that it does not have the intent to sell a debt security and it is more likely than not that it will not have to sell the security before recovery of its cost basis, then an entity may separate other-than-temporary impairments into two components: 1) the amount related to credit losses (recorded in earnings), and 2) all other amounts (recorded in other comprehensive income). This guidance is to be applied prospectively and is effective for interim and annual periods ending after June 15, 2009, with early adoption permitted for periods ending after March 15, 2009. The adoption did not have a material impact on the Company's consolidated financial position or results of operations.

In May 2009, the FASB issued new guidance for accounting for subsequent events. The new guidance, which is now a part of ASC 855, *Subsequent Events,* establishes the accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. The new guidance requires the disclosure of the date through which and entity has evaluated subsequent events and the basis for that date. The Company adopted the new guidance for its interim period ending June, 30, 2009. The adoption of the new guidance and the related disclosures had no impact on the Company's consolidated financial position or results of operations.

3. Other Income (Loss)

During fiscal 2009, the Company recorded $1,200,000 of other income, consisting primarily of a cash settlement from Covidien Ltd. when the Company reached a settlement with Covidien Ltd., Tyco International (US) Inc. and Tyco Health Care Group, L.P., with respect to the lawsuit it 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, Covidien Ltd. paid the Company $3,500,000 (net $1,000,000 after payment of attorney's fees and expenses) and was dismissed from the lawsuit.

During fiscal 2008, the Company recorded a foreign currency transaction loss of $89,000 related to the note payable to Coloplast A/S.

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, Inc and Premier Purchasing Partners, L.P. with respect to the lawsuit. 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 dismissed from the lawsuit.

4. Inventories

Inventories are summarized as follows:

	September 30, 2009	September 30, 2008
Raw materials	$1,983,279	$2,274,199
Work-in-process	3,863,824	3,375,795
Finished goods	3,989,555	3,217,830
Reserve for inventory obsolescence	(126,424)	(121,951)
	$9,710,234	$8,745,873

5. Finite Life Intangible Assets

Finite life intangible assets were as follows:

		September 30, 2009			September 30, 2008		
	Estimated Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net Value	Gross Carrying Amount	Accumulated Amortization	Net Value
Trademarks	8 to 15	$5,423,000	$1,350,586	$4,072,414	$5,423,000	$ 945,410	$4,477,590
Supply agreement	5	634,000	422,670	211,330	634,000	295,870	338,130
Customer relationships	20	2,081,040	346,840	1,734,200	2,314,520	270,027	2,044,493
Totals		$8,138,040	$2,120,096	$6,017,944	$8,371,520	$1,511,307	$6,860,213

Amortization expense related to these assets was as follows:

Year ended September 30, 2009	$632,661
Year ended September 30, 2008	$625,299
Year ended September 30, 2007	$668,165

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

2010	$636,000
2011	$594,000
2012	$509,000
2013	$509,000
2014	$478,000

6. Leases

The Company leases many of its automobiles for its sales staff in the United Kingdom for various terms under long-term, non-cancelable operating lease agreements. The leases expire at various dates through 2013. In the normal course of business, it is expected that these leases will be replaced by leases on other vehicles as the lease terms expire.

Lease expense totaled approximately $312,000, $245,000 and $19,000 during fiscal 2009, 2008 and 2007, respectively.

The following is a schedule by year of estimated future minimum rental payments required under the operating lease agreements:

2010	$252,000
2011	$197,000
2012	$131,000
2013	$ 1,000

7. Shareholders' Equity

Stock Options

The Rochester Medical Corporation 1991 Stock Option Plan authorized the issuance of up to 2,000,000 shares of Common Stock. Under the terms of the 1991 Stock Option Plan, the Board of Directors could 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 could not be less than 85% of the fair market value. 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. As of September 30, 2009, 146,200 options remain outstanding 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. As of September 30, 2009, 88,000 shares remain available for issuance under the 1995 Non-Statutory Stock Option Plan, and there were no options outstanding under the plan.

The 2001 Stock Incentive Plan authorizes the issuance of up to 2,000,000 shares of Common Stock pursuant to grants of incentive stock options, non-qualified options or restricted stock. 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 and restricted stock granted under the 2001 Stock Incentive Plan is determined by the Compensation Committee of the Company's Board of Directors. As of September 30, 2009, 146,500 shares remain available for issuance under the 2001 Stock Incentive Plan, and there were 1,348,500 options outstanding under the plan.

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, 2006	965,000	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	
Balance as of September 30, 2007	564,000	1,777,334	5.90	5.73 years
Options granted	(204,500)	204,500	11.14	
Options exercised	—	(245,700)	5.57	
Options canceled	27,000	(27,000)	20.91	
1991, 1995 Plan — options canceled and not reissuable	(2,000)	—	10.00	
Balance as of September 30, 2008	384,500	1,709,134	6.34	5.70 years
Options granted	(217,000)	217,000	11.29	
Options exercised	—	(364,434)	4.83	
Options canceled	67,000	(67,000)	11.31	
Balance as of September 30, 2009	234,500	1,494,700	$ 7.21	5.74 years
Outstanding options exercisable at end of period		1,062,075	$ 6.04	4.69 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, 2009, 2008 and 2007 was 1,062,075, 1,264,384 and 1,323,334 at a weighted average exercise price of $6.04, $5.36 and $4.96 per share, respectively.

At September 30, 2009, the aggregate intrinsic value of options outstanding was $7,313,983, and the aggregate intrinsic value of options exercisable was $6,428,970. Total intrinsic value of options exercised was $2,848,159 for the year ended September 30, 2009.

As of September 30, 2009, $1,302,539 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 2009, 2008 and 2007 was $6.70, $6.86 and $8.03 per share, respectively. The exercise price of options outstanding at September 30, 2009 ranged from $2.17 to $18.02 per share as summarized in the following table:

Range of Exercise Prices	Number Outstanding at 9/30/09	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share — Total Options Outstanding	Number Exercisable at 9/30/09	Weighted Average Exercise Price Per Share — Options Exercisable
$0.00 — $5.00	686,200	3.3 years	$ 3.19	646,200	$ 3.38
$5.01 — $10.00	150,000	6.4 years	5.91	122,500	5.90
$10.01 — $15.00	653,500	8.2 years	11.64	290,875	11.91
$15.01 — $20.00	5,000	7.5 years	18.02	2,500	18.02
	1,494,700	5.7 years	$ 7.21	1,062,075	$ 6.04

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:

	2009	2008
Dividend yield	0%	0%
Expected volatility	53%	54%
Risk-free interest rate	2.30%	3.09%
Expected holding period (in years)	8.17	8.13
Weighted-average grant-date fair value	$6.70	$6.86

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

8. 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, in addition to certain tax carryforwards. Significant components of deferred income taxes are as follows:

	September 30, 2009	September 30, 2008
Deferred income tax assets:		
Allowance for doubtful accounts	$ 20,457	$ 20,448
Inventory reserves	43,010	44,293
Inventory capitalization	506,438	514,072
Accrued expenses	114,855	56,200
Nonqualified option expense	936,176	994,478
Restricted stock expense	111,360	72,835
Capital loss carryforward	—	37,602
Prepaid taxes on intercompany sales	—	355,556
Charitable contributions	20,996	—
Research and development credits	194,783	—
Net operating loss	342,577	—
ASC 320 unrealized loss	197,678	153,141
Total income tax deferred assets	2,488,330	2,248,625
Deferred income tax liability:		
Depreciation and amortization	565,492	273,395
Net deferred income tax assets	$1,922,838	$1,975,230

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

	September 30, 2009	September 30, 2008
Current assets	$1,153,964	$1,143,931
Noncurrent assets	768,874	831,299
	$1,922,838	$1,975,230

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. The Company has determined it is more likely than not that all deferred tax assets will be realized and therefore no valuation allowance is necessary for the year ended September 30, 2009.

The income (loss) before taxes and the provision for taxes for the years ended September 30, 2009, 2008, and 2007 consist of the following:

	September 30,		
	2009	2008	2007
Income (loss) before taxes:			
U.S.	$1,155,518	$ 317,024	$41,700,139
Non-U.S.	(681,104)	(136,376)	797,690
Total income before taxes	$ 474,414	$ 180,648	$42,497,829
Provision for taxes:			
U.S.			
Current tax expense (benefit)	$ 622,512	$(230,078)	$16,554,431
Deferred tax benefit	(163,393)	(363,176)	(212,801)
Benefit of operating loss carryforwards	—	—	(8,140,581)
Total U.S.	459,119	(593,254)	8,201,049
Non-U.S.			
Current tax expense	1,857	40,238	236,275
Deferred tax expense (benefit)	(95,234)	(25,439)	10,325
Total Non-U.S.	(93,377)	14,799	246,600
Total provision (benefit) for taxes	$ 365,742	$(578,455)	$ 8,447,649

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

	2009	2008	2007
Statutory federal income tax rate	34%	34%	35%
Increase (decrease) in taxes resulting from:			
State taxes	6	28	2
Foreign taxes	29	52	1
Tax exempt interest	—	(142)	(1)
ASC 718 on incentive stock options	28	59	—
Change in valuation allowance and utilization of net operating loss carryforward	—	—	(17)
R&D credits	(38)	(310)	—
Change in reserves	(2)	129	—
Rate adjustment on deferred taxes	—	(109)	—
DPAD	8	(70)	—
Other	12	9	—
Effective income tax rate	77%	(320)%	20%

On October 1, 2007, the Company adopted accounting provisions that now form part of ASC 740, *Income Taxes*, and which clarify the accounting for uncertainty in tax positions recognized in the financial statements. These provisions create a single model to address uncertainty in tax positions and clarifies the accounting for income taxes by prescribing the minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. ASC 740 also provides guidance on derecognition, measurement,

classification, interest and penalties, accounting in interim periods, disclosure and transition. At the adoption date, October 1, 2007, the Company did not have a material liability for unrecognized tax benefits. As of September 30, 2009, the Company has recognized approximately $56,000 for unrecognized tax benefits. If the Company were to prevail on all unrecognized tax benefits recorded at September 30, 2009, the total gross unrecognized tax benefit totaling approximately $56,000 would benefit the Company's effective tax rate if recognized.

It is the Company's practice to recognize penalties and/or interest to income tax matters in income tax expenses. As of September 30, 2009, the Company did not have a material amount of accrued interest or penalties related to unrecognized tax benefits.

The Company is subject to income tax examinations in the U.S. Federal jurisdiction, as well as in the United Kingdom and various state jurisdictions. The Internal Revenue Service completed an examination of our income tax return for the fiscal year ended September 30, 2007, and a settlement was reached in September 2009. ASC 740 reserves relating to the settlement items were more than the additional taxes assessed by the IRS. The remaining ASC 740 reserves relating to the 2007 tax year were released during the year ended September 30, 2009, as a result of the settlement.

A reconciliation of the beginning and ending amount of unrecognized tax benefit is as follows:

Balance at October 1, 2008	$ 239,496
Increases/(decreases) as a result of tax positions taken during a prior period	21,764
Increases/(decreases) as a result of tax positions taken during the current period (including interest)	27,175
Decreases for tax positions related to acquired entities during a prior period	0
Reductions as a result of lapse of the applicable statute of limitations	0
Decreases relating to settlements with taxing authorities	(232,546)
Balance at September 30, 2009	$ 55,889

9. Related Party Transactions

The brother-in-law of the CEO and President, has performed legal services for the Company. During the years ended September 30, 2008 and 2007, the Company incurred legal fees and expenses of approximately $3,000 and $34,000, 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. There were no expenses incurred for legal fees from this related party during the year ended September 30, 2009.

10. Significant Customers

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

	September 30,		
	2009	2008	2007
Significant customers:			
Hollister	12%	12%	15%
Coloplast and Coloplast subsidiaries	10	14	16
Total	22%	26%	31%

11. 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 years ended September 30, 2009, 2008 and 2007 was $136,497, $120,536 and $70,817, respectively.

12. Geographic Area Data

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

	September 30,		
	2009	2008	2007
Sales:			
United States	$14,446,788	$14,143,490	$13,925,808
Europe	18,794,401	19,107,071	16,777,866
Rest of world	1,557,640	1,941,388	1,959,413
Total	$34,798,829	$35,191,949	$32,663,087

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, excluding deferred income tax assets of the Company are located in the United States and Europe as follows:

	September 30,	
	2009	2008
Long-lived assets:		
United States	$12,936,346	$13,557,637
Europe	7,638,386	8,582,924
Total	$20,574,732	$22,140,561

13. Line of Credit and Long-Term Debt

In June 2006, in conjunction with an asset purchase agreement with Coloplast A/S, 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 and payable in five equal annual installments of $1,068,000 payable annually on June 2. The Company has imputed interest on the note at 6.90% which reflected the Company's cost of borrowing at the date of the purchase agreement and the discount is being amortized over the life of the note. The liability balance was $1,927,910 and $2,796,929 at September 30, 2009 and 2008, respectively.

In June 2006, we entered into a $7,000,000 credit facility with U.S. Bank National Association. The credit facility consisted of a $5,000,000 term loan payable in five years and accruing interest at a rate equal to 4.77%, and a revolving line of credit of up to $2,000,000, maturing annually on March 31, with interest payable monthly at a floating rate based on the quoted one-month LIBOR rate plus 1.60%. In March 2009, we paid off the entire term loan and terminated the revolving line of credit.

In February 2009, we entered into a $14,000,000 credit facility with UBS Financial. The credit facility consists of a revolving line of credit of up to $14,000,000 with interest accruing monthly at a floating rate based on the quoted one-month LIBOR rate plus 1.25%. As of September 30, 2009 we had an outstanding balance of $1,878,447 under the revolving line of credit. Our obligations under the credit facility are payable on demand and are secured by our investments in marketable securities held at UBS.

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

2010	$2,786,622
2011	1,019,735
Total	$3,806,357

14. Share Repurchase Program

On March 3, 2009, the Company announced its intention to repurchase some of its outstanding common shares pursuant to its previously authorized share repurchase program. Up to 2,000,000 shares may be repurchased from time to time on the open market, or pursuant to negotiated or block transactions, in accordance with applicable Securities and Exchange Commission regulations. During the three months ended September 30, 2009, no shares were repurchased. During fiscal 2009, the Company repurchased 110,653 shares of common stock pursuant to this program at an average price of $9.56 per share. Total cash consideration for the repurchased shares was approximately $1,100,000. As of September 30, 2009, there remained 1,847,347 shares that may be purchased under the program.

15. Quarterly Results (Unaudited)

Summary data relating to the results of operations for each quarter of the years ended September 30, 2009 and 2008 follows (in thousands, except per share amounts):

	Three Months Ended			
	December 31	March 31	June 30	September 30
Fiscal year 2009:				
Net sales	$8,436	$8,445	$8,909	$9,009
Gross profit	3,925	4,414	4,184	4,303
Income (loss) from operations	(325)	(90)	(161)	(173)
Net income (loss) before taxes	(40)	864	(176)	(172)
Net income (loss) per common share — basic	$ .00	$ .03	$ (.01)	$ (.02)
Net income (loss) per common share — diluted	$ .00	$ .03	$ (.01)	$ (.02)
Fiscal year 2008:				
Net sales	$8,223	$9,215	$8,241	$9,512
Gross profit	4,141	4,272	3,672	4,622
Income (loss) from operations	72	(429)	(458)	322
Net income (loss) before taxes	376	(202)	(342)	348
Net income (loss) per common share — basic	$ .02	$ (.01)	$ .03	$ .03
Net income (loss) per common share — diluted	$ .02	$ (.01)	$ .02	$ .03

16. Subsequent Events

The Company evaluated its September 30, 2009 financial statements for subsequent events through December 11, 2009, the date the financial statements were available to be issued. The Company is not aware of any subsequent events which would require recognition or disclosure in the financial statements.

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

On March 11, 2008, the Audit Committee of the Board of Directors of Rochester Medical Corporation, after a review of proposals for audit services from several public accountants, decided to engage Grant Thornton LLP as our independent registered public accounting firm for the fiscal year commencing October 1, 2007 and ending September 30, 2008. McGladrey & Pullen LLP ("McGladrey & Pullen"), the then-current independent registered public accounting firm, was dismissed by the Audit Committee as of March 11, 2008.

In connection with the audit of the fiscal year ended September 30, 2007, and the subsequent interim period through March 11, 2008, there were no disagreements between us and McGladrey & Pullen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of McGladrey & Pullen, would have caused McGladrey & Pullen to make reference in connection with their opinion to the subject matter of the disagreement.

There were no reportable events (as defined in Regulation S-K Item 304(a)(1)(v)) during our two most recent fiscal years ended September 30, 2007, or the subsequent interim period through March 11, 2008.

The audit reports of McGladrey & Pullen on our consolidated financial statements as of and for the years ended September 30, 2007 and September 30, 2006 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles.

A letter from McGladrey & Pullen LLP is included as Exhibit 16 to this Form 10-K.

On March 13, 2008, the Audit Committee engaged Grant Thornton as our independent registered public accounting firm. During our two most recent fiscal years and the subsequent interim period through February 29, 2008, we did not consult with Grant Thornton LLP regarding any of the matters set forth in Item 304(a)(2)(i) and (ii) of Regulation S-K.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. As of the end of the period covered by this report (the Evaluation Date) we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of 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 (the Exchange Act)). Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

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 Grant Thornton 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", the information contained under the heading "Section 16(a) Beneficial Ownership Reporting Compliance" and the information contained under the heading "Corporate Governance — Board Meetings and Committees — Audit Committee" 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, 2009, 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, 2009, (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 information contained under the heading "Proposal No. 2 — Proposal to Approve the Rochester Medical Corporation 2010 Stock Incentive Plan — Equity Compensation Plan Information" 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, 2009, is incorporated herein by reference.

(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, 2009, 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, 2009, 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 Auditor" 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, 2009, 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, 2009 and 2008.

(ii) Consolidated Statements of Operations for the years ended September 30, 2009, 2008 and 2007.

(iii) Consolidated Statement of Shareholders' Equity and Comprehensive Income (Loss) for the years ended September 30, 2009, 2008 and 2007.

(iv) Consolidated Statements of Cash Flows for the years ended September 30, 2009, 2008 and 2007.

(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. (Incorporated by reference to Exhibit 3.1 of Registrant's Current Report on Form 8-K filed on June 12, 2009).
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†	Form of Change of Control Agreement between the Company and each of its executive officers. (Incorporated by reference to Exhibit 10.10 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.6†	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).
10.7	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).
10.8	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).
10.9	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).
10.10†	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).
10.11†	The Company's Fiscal 2009 Management Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 24, 2008).
10.12	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).
10.13	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).

10.14	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).
10.15	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).
10.16	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).
16	Letter from McGladrey & Pullen LLP, (Incorporated by reference to Exhibit 16.1 of the Registrant's Current Report on Form 8-K filed on March 14, 2008)
21*	Subsidiaries of the Company
23.1*	Consent of Grant Thornton LLP.
23.2*	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).

* 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 and, Chief Executive Officer

Dated: December 11, 2009

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 and Chief Executive Officer (principal executive officer)
/s/ David A. Jonas David A. Jonas	Director, Chief Financial Officer, Treasurer and Secretary (principal financial and accounting officer)
* Darnell L. Boehm	Director
* Roger W. Schnobrich	Director
* Benson Smith	Director

*By: David A. Jonas
David A. Jonas
Attorney-in-Fact

Dated: December 11, 2009

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

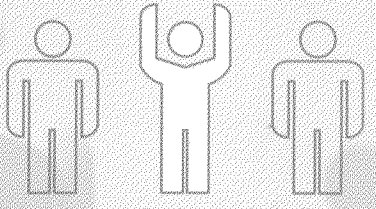
COL. A	COL. B	COL. C		COL. D	COL. E
		Additions		(1), (2)	
Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts — Describe	Deductions — Describe	Balance at End of Period
Year ended September 30, 2009:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 65,202	$ —	—	$ 1,833	$ 63,369
Allowance for inventory obsolescence	121,951	52,512	—	48,039	126,424
Year ended September 30, 2008:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$ 57,913	$ 10,807	—	$ 3,518	$ 65,202
Allowance for inventory obsolescence	117,027	104,196	—	99,272	121,951
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

(1) Uncollectible accounts written off net of recoveries

(2) Obsolete inventory written off against the allowance

INDEX TO EXHIBITS

Exhibit	
21	Subsidiaries of the Company.
23.1	Consent of Grant Thornton LLP
23.2	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)



INNOVATIVE

Rochester® MEDICAL

One Rochester Medical Drive • Stewartville, MN 55976 USA
507-533-9600 • US Toll-Free: 800-615-2364 • www.rocm.com