Rochester MEDICAL

ONE PIECE AT A TIME...

two thousand and eleven annual report

80 COUNTRIES WORLDWIDE

China
India
Kuwait
Lebanon
Syria
Venezuela
Colombia
Jordan
Pakistan
Russia
Belarus
Ukraine
Lithuania
Estonia
Latvia
Canada
Argentina
Brazil
Chile
Costa Rica
Mexico
Trinidad
Botswana
Ghana
Lesotho
Republic of S.A.

NETHERLANDS

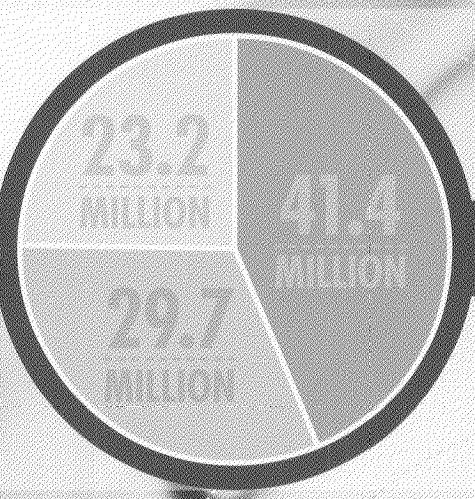
Swaziland
Egypt
Israel
Qatar
Saudi Arabia
U.A.E.
Austria
Belgium
Croatia
Denmark
England
Finland
France
Germany
Greece
Ireland
Italy
Norway
Poland
Portugal
Scotland
Slovenia
Spain
Sweden
Switzerland
Turkey
Hong Kong
Indonesia
Japan
Korea
Malaysia
Singapore
Taiwan
Australia
New Zealand
Peru

$52.9 millions

TOTAL 2011 SALES

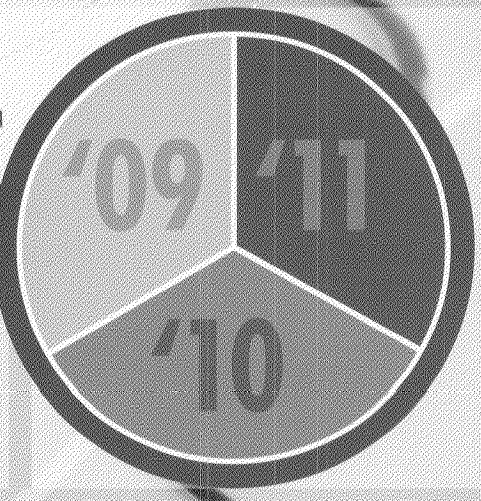
39.2%

ROCM DIRECT SALES GROWTH 2011



PRIVATE label

3 YEAR SNAPSHOT



11.5

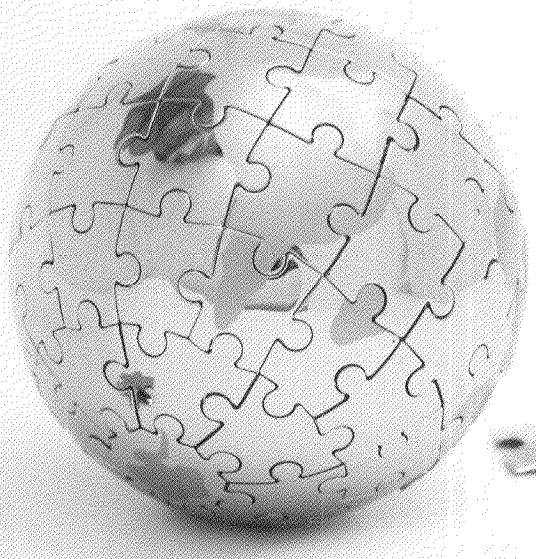
ON AVERAGE *

Some of finest medical device companies in the world have recognized the quality of our unique technology, giving them the confidence to sell selected ROCM products under their own brand.

consistent sales

a perfect fit... 2011

IN OVER



"We are very excited that Laprolan is now a Rochester Medical Company. It's amazing to find two companies that fit together nicely in every respect."

– Gerard de Jong: *General Manager, Laprolan* –

Welcoming **LAPROLAN** to the Rochester Medical Team

Rochester Medical's newest addition, Laprolan, is a supplier of medical devices in The Netherlands which specializes in the sales, marketing, and distribution of high-quality products in the fields of urology, continence care, wound care, and ostomy.

They are a great group of people and Rochester Medical is delighted to have them as part of our team.

THE LAPROLAN TEAM

TOP *(L-R):* Remko van Oss, *Back Office Manager;* Gerard de Jong, *General Manager;* Ton Mulder, *Marketing Manager*

BOTTOM *Standing (L-R):* Rinske Makaske, Gerard de Jong, Andre Bouwmeester, Rianne de Leeuw, Tom Hendriks, Remko van Oss, Jan de Haas, Elke Rossen, Rene Abelmann, Linda de Swart, Silvia Groenen, Ton Mulder, Ester Kohrman, Marijke Moll, Yvonne Maase, Wiet Kamp, Ilse de Bergh; *Kneeling (L-R):* Marion van Veen, Ingrid Bruisten, Suzanne van Emden

DEAR SHAREHOLDERS:

CEO & President, Anthony J. Conway

2011 was an eventful and exciting year for Rochester Medical Corporation.

With the acquisition of Laprolan in The Netherlands, the significant growth in the U.S. Sales and Marketing Team, and the continuing excellent performance of Rochester Medical Ltd. in the United Kingdom we are stronger than ever and well prepared for the future.

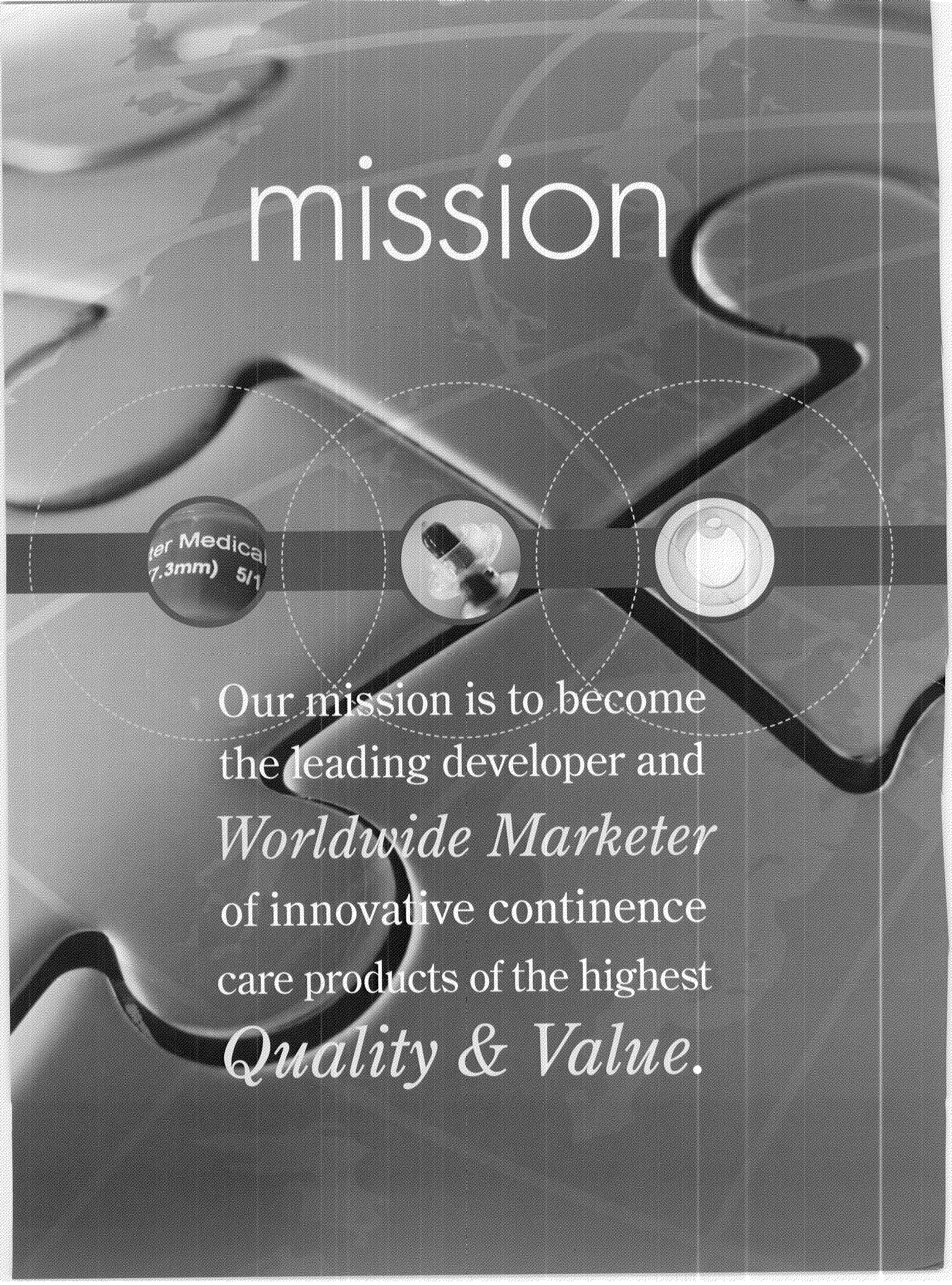
The Laprolan acquisition gives us a direct sales force in The Netherlands and can serve as a base for direct expansion into other countries in mainland Europe. It also broadens our product lines with a selection of Wound Care and Ostomy Products.

The 2011 significant increase in the U.S. Home Care and Acute Care Sales and Marketing force has started to nicely accelerate sales, and we expect good growth in the U.S. going forward.

Rochester Medical Ltd. had an excellent year and we expect continued solid progress in the United Kingdom.

The Company is stronger than ever due to excellent employees, world class technology, and ongoing shareholder support. Special thanks to all of you for making our continued growth possible. We anticipate another successful year ahead!

mission



Our mission is to become
the leading developer and
Worldwide Marketer
of innovative continence
care products of the highest
Quality & Value.

two thousand and eleven corporate information

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: Chairman, President and Chief Executive Officer of Teleflex Incorporated, a manufacturer/distributor of medical devices. Mr. Smith also currently serves on the board of Zoll Medical Corporation, where he also holds the position of Chairman. He also serves on a variety of academic and health-related organizations.

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 of Marketing & U.S. Sales

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 – Suite 1500
Minneapolis, Minnesota 55402-1498 USA

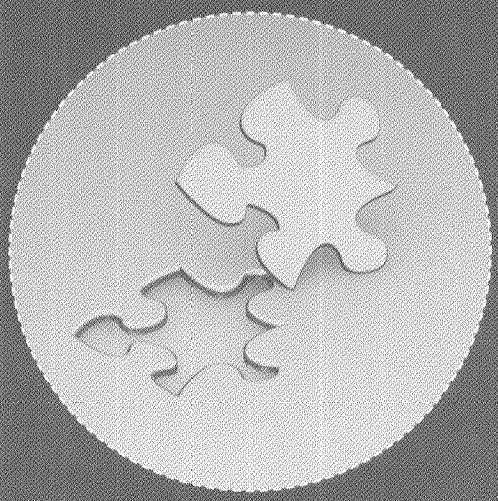
Stock Transfer Agent & Registrar: Wells Fargo
P.O. Box 64854
Saint Paul, Minnesota 55164-0854 USA
US Toll-Free: 800-468-9716

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 2010	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Fiscal High	$11.88	$13.80	$13.12	$11.17
Fiscal Low	$10.11	$11.50	$9.44	$8.56
FQ 2011	**Quarter 1**	**Quarter 2**	**Quarter 3**	**Quarter 4**
Fiscal High	$11.74	$11.48	$11.58	$9.43
Fiscal Low	$10.30	$10.03	$8.28	$7.45

Form 10-K Availability:
Copies of the Company's Form 10-K for the 2011 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



Rochester® MEDICAL

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

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

FORM 10-K

☒ **Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For fiscal year ended September 30, 2011

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
Commission File Number: 0-18933

Rochester Medical Corporation

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

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

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

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

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

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

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

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

Indicate by 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 checkmark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See 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 ☐

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, 2011 ($11.48) was $121,841,430.

Number of shares of common stock outstanding on December 5, 2011 was 12,101,867 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's Proxy Statement for its 2012 Annual Meeting of Shareholders are incorporated by reference in Part III.

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PART I

ITEM 1. Business

Rochester Medical Corporation ("we," "our," or "us") develops, manufactures and markets, domestically and internationally, a broad line of innovative, technologically enhanced PVC-free and latex-free urinary continence and urine drainage care products for the home and acute care markets. Acute care markets are generally hospitals and extended care treatment facilities, while home care users are generally patients who use our products at home. We also sell certain ostomy and wound and scar care products and other brands of urological products into the European marketplace.

Our home care products include a full line of silicone male external catheters for managing male urinary incontinence and a line of intermittent catheters for managing both male and female urinary retention, including our *Magic 3*™ advanced line of silicone intermittent catheters. Along with our silicone male external catheters, we also sell a line of latex male external catheters in the United Kingdom. Our home care products also include the *FemSoft® Insert*, a soft, liquid-filled, conformable urethral insert for managing stress urinary incontinence in adult females. Our acute care products include a line of standard Foley catheters, our *Strata* brand of advanced Foley catheters, and 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 home care products also are used in the acute care market.

The primary purchasers of our products are distributors, individual hospitals and healthcare institutions, and extended care facilities. We market our products under our *Rochester Medical®* brand through a direct sales force in the United States, the United Kingdom and the Netherlands, and through independent distributors in other international markets. We also market our *Rochester Medical®* branded products to Group Purchasing Organizations. A portion of our products are supplied to several large medical product companies for sale under private label brands owned by these companies.

Home 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 MECs: 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 MECs. 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 MECs. 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 MECs are transparent, permitting visual skin inspection without removal of the catheters and aiding proper placement of the catheters. Our MECs 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 MECs 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 offer 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, who will fit the patient with the proper size and instruct the patient on proper application of the *FemSoft Insert*. The *FemSoft Insert* has been approved for inclusion in Part IX of the U.K. Drug Tariff as a prescription product that is reimbursable under the U.K. National Healthcare System (NHS). In the U.S., the Centers for Medicare & Medicaid Services (CMS) has issued a specific reimbursement code which covers our *FemSoft Insert*. We believe the availability of NHS and Medicare reimbursement 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.

We also offer our *StrataSI*™ and *StrataNF*™ advanced silicone Foley catheters. The improved silicone design consists of a soft, pliable inner core surrounded by ultra-soft, ultra-smooth outer layers allowing for softness and flexibility which 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 from the catheter during the period the catheter is in the patient.

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.

Other Products

Through our newly acquired subsidiary, Laprolan B.V., we distribute into the European marketplace certain *LaproCare*™ ostomy and wound and scar care products and accessories, anti-decubitis mattresses and other brands of urological products in addition to our own *Rochester Medical*® branded products. Laprolan has been an importer and distributor of medical products since 1986, and markets its products and services exclusively to healthcare institutions, physicians and specialty nurses.

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

The primary purchasers of our products are distributors, individual hospitals and healthcare institutions, and extended care facilities. We market our products under our *Rochester Medical*® brand through a direct sales force in the United States, the United Kingdom and the Netherlands, and through independent distributors in other international markets. As part of our three year strategic business plan through fiscal 2013, we increased the level of investment in our sales and marketing programs in fiscal 2011 to support our direct sales growth in the U.S. and Europe through the addition of more than 30 members to our sales team. As of September 30, 2011, our U.S.

direct sales force consisted of thirty-four members. Internationally, we sell our *Rochester Medical*® branded products in the United Kingdom through a direct sales force of nineteen members, and in the Netherlands through a direct sales force of eight members as of September 30, 2011, respectively.

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 international markets where currently we do not maintain a direct sales presence. Private label sales comprised 22% of total sales in fiscal 2011. In fiscal 2010 and fiscal 2009, private label sales comprised 28% and 33% of total sales, respectively. Sales to Coloplast and to Hollister Incorporated ("Hollister") under private label arrangements accounted for 10% and 9% of net sales for fiscal 2011, 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 the GPOs. We currently have a national Group Purchasing Contract for urological products with Premier Purchasing Partners, L.P. ("Premier") through February 2013. 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), MECs, intermittent catheters, and urethral inserts.

Similarly, we have an Innovative Technology Contract with Novation, LLC ("Novation") through June 2013 for our urological catheter products and related accessories, including our advanced infection control catheters. Novation provides contracting services to more than 25,000 members of VHA, Inc. and the University HealthSystem Consortium, or UHC, and more than 15,000 customers of Provista (formerly HPPI). We have also been awarded a urological products contract with Broadlane Inc. through October 2014. 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. MedAssets, Inc. ("MedAssets") acquired The Broadlane Group in November 2010, and our contract with Broadlane was transitioned over to MedAssets in November 2011. MedAssets is a GPO with 180 health systems, 4,000 hospitals and 90,000 non-acute healthcare providers.

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.

We rely on arrangements with medical product companies and independent distributors to sell our products in Europe (except in the U.K. and the Netherlands) 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 (including the U.K. and the Netherlands) accounted for 65%, 59% and 58% of total sales in fiscal 2011, 2010 and 2009, respectively.

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 Private Label Distribution Agreement with Coloplast, we supply silicone MECs to be sold under Coloplast's brands worldwide, excluding the United Kingdom, through December 2015. Through a Private Label Agreement with Hollister, we supply silicone MECs to be sold under the Hollister brand worldwide through December 2014.

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. A 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, MEC, 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. An FDA audit of our facilities was successfully completed in 2009.

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 December 2015, 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

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 resistant organisms to develop 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 UTIs. 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 home care setting and do not make clinical claims for our antibacterial intermittent catheters used in that setting.

Research and development expense for fiscal years 2011, 2010 and 2009 was $1,009,000, $1,235,000 and $1,241,000, 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 GPOs. 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 A/S, Covidien PLC, Hollister and Coloplast. Many of the competitive alternative products or therapies are distributed by larger competitors including Johnson & Johnson, Kimberly-Clark Corporation and The Proctor & Gamble Company. Many of our competitors, potential competitors and providers of alternative products or therapies have significantly greater financial, manufacturing, marketing, distribution and technical resources and experience than us. It is possible that other large healthcare and consumer products companies may enter this market in the future. Furthermore, academic institutions, governmental agencies and other public and private research organizations will likely continue to conduct research, seek patent protection and establish arrangements for commercializing products in this market. Such products may compete directly with our products.

Patents and Proprietary Rights

Our success depends in part upon 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, the most recent 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.

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.

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, 2011, we employed 328 full-time employees, of whom 175 were in manufacturing, 100 in sales and marketing, and the remainder in research and development and administration. As of such date, we also had 55 contract employees in manufacturing. 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	67	Chairman of the Board, Chief Executive Officer and President
Robert M. Anglin	44	Vice President, Quality and Regulatory
James M. Carper	60	Vice President, U.S. Sales and Marketing
Philip J. Conway	55	Vice President, Production Technologies
David A. Jonas	47	Director, Chief Financial Officer, Treasurer and Secretary
Martyn R. Sholtis	52	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. 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 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 serves as our Vice President of Quality and Regulatory. 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 serves as our Vice President of U.S. Sales and Marketing, and is responsible for all direct sales activity in the United States. 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, serves as our Vice President of Production Technologies. 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 20 have resulted in issued U.S. patents and 32 have resulted in issued foreign patents.

David A. Jonas serves as our Chief Financial Officer, Treasurer and as our Secretary. Mr. Jonas has also served as a member of our Board of Directors since 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 corporate business development activities, private label sales and also leads our international sales team. 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

On April 7, 2011, we completed the acquisition of the outstanding capital stock of Laprolan B.V., a corporation organized under the laws of The Netherlands and a wholly owned subsidiary of Fornix BioSciences N.V., pursuant to a Share Purchase Agreement. As provided in the Share Purchase Agreement, the transaction has a retroactive effective date of January 1, 2011, and the operating results of Laprolan are for our account from and after January 1, 2011. We have applied purchase accounting as of that date and have included the results of Laprolan in our financial statements beginning in the second quarter of our fiscal 2011. At closing, we paid to Fornix €10,474,974 (US$15,057,775, of which $60,217 was paid for the cash balance of Laprolan on January 1, 2011 and $119,433 was interest from January 1, 2011 until closing).

Laprolan B.V. distributes into the European marketplace certain *LaproCare*™ ostomy and wound and scar care products and accessories, anti-decubitis mattresses and other brands of urological products in addition to our own *Rochester Medical*® branded products. Laprolan has been an importer and distributor of medical products since 1986, and markets its products and services exclusively to healthcare institutions, physicians and specialty nurses.

As part of our three year strategic business plan through 2013, we increased the level of investment in our sales and marketing programs in fiscal 2011 to support our direct sales growth in the U.S. and Europe through the addition of more than 30 members to our sales team. As of September 30, 2011, our U.S. direct sales force consisted of thirty-four members. Internationally, we sell our *Rochester Medical*® branded products in the United Kingdom through a direct sales force of nineteen members, and in the Netherlands through a direct sales force of eight members as of September 30, 2011, respectively.

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.

We have a limited history of profitability and our strategic business plan may not produce the intended growth in revenue and operating income

Our net loss for the fiscal year was ($1,315,000) in fiscal 2011 and was ($254,000) for fiscal 2010, while net income for our fiscal year 2009 was $109,000. The objective of our three year strategic plan that we adopted at the beginning of fiscal 2011 is to double our annual overall sales during the three fiscal years of the plan, while also producing net income in an estimated range of $9 to $10 million in the third fiscal year. As part of that plan, we increased the level of investment in our sales and marketing programs in fiscal 2011 to support our direct sales growth in the U.S. and Europe through the addition of more than 30 members to our sales team. We expect the increased investment in sales and marketing programs to be funded primarily through cash generated from operations. Additionally, 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. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the accelerated revenue growth we are targeting or the bottom line results that we anticipate. 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.

In addition, as part of our strategy for growth, we may make acquisitions and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. In this regard, acquisitions involve numerous risks, including difficulties in the integration of the operations, technologies, services and products of the acquired companies and the diversion of management's attention from other business concerns. Although our management will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will properly ascertain all such risks. In addition, acquisitions could result in the incurrence of substantial additional indebtedness and other expenses or in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and 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 2011 represented approximately 30% 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.

Our products may not succeed in the market

We have several products, including the antibacterial hydrophilic 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 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, until 2007 we had been unsuccessful 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. GPOs typically award contracts on a category-by-category basis through a competitive bidding process. We have a national GPO contract for urological products with Premier Purchasing Partners, L.P., one of the largest GPOs in the United States, through February 2013 for our Foley catheters (including our infection control catheters), MECs, intermittent catheters, and urethral inserts. Similarly, we have an Innovative Technology Contract with Novation, LLC through June 2013 for our urological catheter products and related accessories, including our advanced infection control catheters. We also have a urological products contract with Broadlane Inc. (now MedAssets, Inc.) through October 2014. There can be no assurance, however, that these contracts will generate significant sales, that the contracts will be renewed beyond their current 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.

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 upon 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 decreased 2% in fiscal 2011 compared to fiscal 2010, and represented 22% of total sales in fiscal 2011 compared to 28% in fiscal 2010. 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 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. Many of our competitors also have substantially more marketing and sales experience than us and substantially larger sales forces and greater resources to devote to such efforts. We increased the level of investment in our sales and marketing programs in fiscal 2011 to support our direct sales growth in the U.S. and Europe through the addition of more than 30 members to our sales team. There can be no assurance that our investment in our sales and marketing programs will produce the results we expect or 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.

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.

In March 2010, significant health care reform was enacted into law in the United States, which included a number of provisions aimed at improving quality and decreasing costs. It is uncertain what consequences these provisions will have on patient access to new technologies and what impacts these provisions will have on Medicare reimbursement rates. Further legislative or administrative reforms to the U.S. or international reimbursement systems that significantly reduce reimbursement for our products or deny coverage for such products, 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 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.

Our business, financial condition, results of operations and cash flows could be significantly and adversely affected by recent healthcare reform legislation and other administration and legislative proposals

The Patient Protection and Affordable Care Act and Health Care and Educational Reconciliation Act (the Acts) were enacted into law in March 2010. Certain provisions of the Acts will not be effective for a number of years and there are many programs and requirements for which the details have not yet been fully established or consequences not fully understood, and it is unclear what the full impacts will be from the legislation. The legislation levies a 2.3% excise tax on all U.S. medical device sales beginning in 2013, which tax may materially and adversely affect our business and results of operations. In fiscal 2011, this would have equated to an excise tax of approximately $423,000. The legislation also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs. It is uncertain at this point what negative unintended consequences these provisions will have on patient access to new technologies. The Medicare provisions include value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals starting in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. We cannot predict what healthcare programs and regulations will be ultimately implemented at the federal or state level, or the effect of any future legislation or regulation. However, any changes that lower reimbursements for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

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 significant 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. Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to even more rigorous regulation by foreign governmental authorities in the future. Penalties for a company's noncompliance with foreign governmental regulation could be severe, including revocation or suspension of a company's business license and criminal sanctions. 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 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 65% of our net sales in fiscal 2011. 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 subsidiaries Rochester Medical Limited and Laprolan B.V., we are exposed to foreign currency exchange rate fluctuations due to transactions denominated primarily in British pounds or euros, which may potentially reduce the U.S. dollars we report for sales denominated in British pounds or euros and/or increase the U.S. dollars we report as expenses in British pounds or euros, 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 or increases in regulatory requirements, surtaxes, tariffs, customs duties or other trade barriers;

- weaker intellectual property rights protection in some countries; and
- political and economic instability, including concerns over excessive levels of national debt and budget deficits in countries where we market our products that could result in an inability to pay or timely pay outstanding payables.

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

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

We 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. As part of our strategic plan, we have significantly expanded our U.S. sales and marketing presence. 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 depends 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 $7 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.

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

Financial markets and the economies in the United States and internationally may continue to experience disruption and volatility as they have in recent years. The current economic environment may, among other things, create downward pressure on the pricing of our products, affect the collection of accounts receivable, increase the sale cycle of certain of our products, slow the adoption of new technology, and adversely affect our customers, causing them to reduce spending. Although there are some indications that the economy in the United States has begun to recover, the strength and timing of an economic recovery remains uncertain, which could continue to adversely affect our operations and results in fiscal 2012. The economies of Europe and other regions may also remain distressed well into 2012 or longer, which could continue to adversely affect our operations and results in fiscal 2012. There can be no assurance that there will not be further deterioration in the global economy, and we cannot predict to what extent a continued global economic slowdown may negatively impact our net sales and profit margins, sales volumes and reimbursement rates from third party payors.

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 and financial conditions and to 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 operations 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 operations occupy 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. In fiscal 2010, we constructed 3,000 square feet of chemical storage space as an addition to our MEC and Foley catheter manufacturing facility. We also own a 13,000 square foot office building/warehouse in Lancing, England and a 18,000 square foot office building/warehouse in Beuningen, the Netherlands. 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 facilities in Stewartville, Minnesota could be expanded if the need arises.

ITEM 3. Legal Proceedings

We are not subject to any 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.

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 2010		
First Quarter	$11.88	10.11
Second Quarter	13.80	11.50
Third Quarter	13.12	9.44
Fourth Quarter	11.17	8.56
Fiscal 2011		
First Quarter	$11.74	10.30
Second Quarter	11.48	10.03
Third Quarter	11.58	8.28
Fourth Quarter	9.43	7.45

Repurchases of Equity Securities

In December 1999, our 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 fiscal 2011, we repurchased a total of 284,585 shares of common stock pursuant to this program. The following table summarizes our share repurchases during the three months ended September 30, 2011:

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans	Maximum Number of Shares that May Yet be Purchased Under the Plan
July 1, 2011 – July 31, 2011	—	—	413,319	1,586,681
August 1, 2011 – August 31, 2011	103,134	$8.69	516,453	1,483,547
September 1, 2011 – September 30, 2011	53,700	$8.08	570,153	1,429,847

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

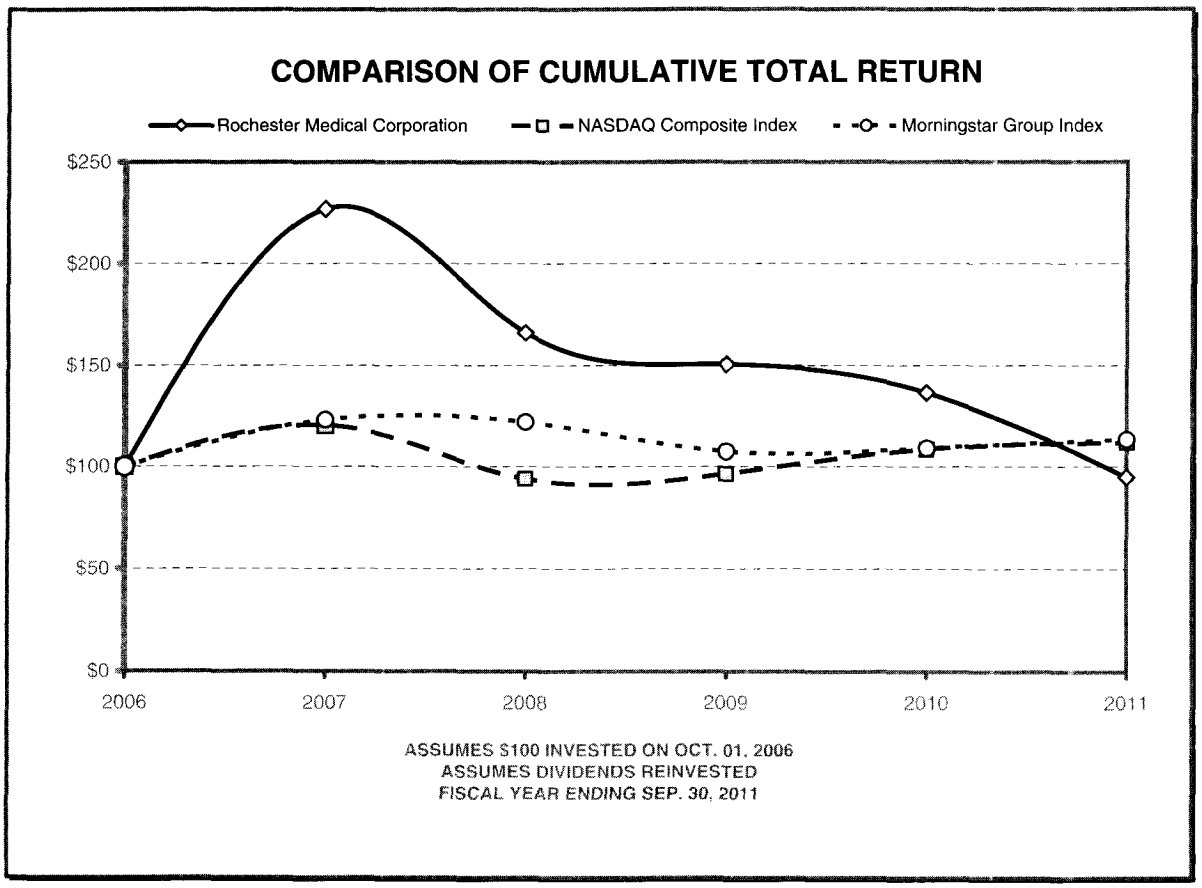
As of December 5, 2011, we had 122 shareholders of record. Such number of record holders does not reflect shareholders who beneficially own common stock in nominee or street name.

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 Morningstar Group Medical Instruments and Supplies Index during the five fiscal years ended September 30, 2011. The comparison assumes $100 was invested on October 1, 2006 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.



	Fiscal Year Ending September 30,					
	2006	2007	2008	2009	2010	2011
Rochester Medical Corporation	$100	$226.87	$165.75	$150.50	$136.37	$ 94.87
Morningstar Group Medical Instruments and Supplies Index	100	122.94	122.08	107.21	108.92	113.26
Nasdaq Composite Index	100	120.42	93.94	96.31	108.45	111.66

ITEM 6. Selected Financial Data

The following selected financial data of Rochester Medical Corporation as of September 30, 2011and 2010 and for the fiscal years ended September 30, 2011, 2010 and 2009, is derived from, and should be read together with, our consolidated financial statements audited by Grant Thornton, LLP, our independent auditors. The following selected financial data as of September 30, 2009, 2008 and 2007 and for the fiscal years ended September 30, 2008 and 2007 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,				
	2011	2010	2009	2008	2007
	(In thousands, except for per share data)				
Net sales	$52,919	$41,443	$34,799	$35,192	$32,663
Cost of sales	26,821	21,739	17,973	18,484	15,619
Gross profit	26,098	19,704	16,826	16,708	17,044
Operating expenses:					
Marketing and selling	18,967	11,869	10,327	9,499	6,490
Research and development	1,009	1,235	1,241	1,044	943
General and administrative	7,799	6,391	6,007	6,658	6,743
Total operating expenses	27,775	19,495	17,575	17,201	14,176
Income (loss) from operations	(1,677)	209	(749)	(493)	2,868
Other income	—	—	1,200	1,240	38,855
Interest income (expense), net	(261)	61	24	(566)	775
Net income (loss) before income tax	(1,938)	270	475	181	42,498
Income tax benefit (expense)	623	(524)	(366)	578	(8,448)
Net income	$(1,315)	$ (254)	$ 109	$ 759	$34,050
Net income (loss) per common share — basic	$ (.11)	$ (.02)	$ .01	$ .06	$ 2.97
Net income (loss) per common share — diluted	$ (.11)	$ (.02)	$ .01	$ .06	$ 2.77
Weighted average number of common shares outstanding — basic	12,218	12,182	12,045	11,816	11,450
Weighted average number of common shares outstanding — diluted	12,218	12,182	12,640	12,577	12,272

	As of September 30,				
	2011	2010	2009	2008	2007
	(in thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$34,905	$35,513	$36,262	$37,002	$37,137
Working capital	34,211	47,605	48,552	48,772	46,325
Total assets	91,139	75,666	75,965	76,983	75,495
Long-term debt and capital lease obligations	1,566	46	1,076	4,046	6,066
Retained earnings	13,263	14,579	14,833	14,724	13,964
Total shareholders' equity	65,977	68,893	68,820	67,699	64,509

No dividends were declared or paid in any year from 2007 to 2011.

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 home and acute care markets. Acute care markets are generally hospitals and extended care treatment facilities, while home care users are generally patients who use our products at home. The home care products we manufacture include our silicone male external catheters, our standard and advanced lines of silicone and anti-infection intermittent catheters and our *FemSoft Insert*. The acute care products we manufacture include our standard and advanced lines of silicone and anti-infection Foley catheters. Through our newly acquired subsidiary, Laprolan B.V., we also sell certain ostomy and wound and scar care products and other brands of urological products. The primary purchasers of our products are distributors, individual hospitals and healthcare institutions, and extended care facilities. We sell our products directly and through private label partners, both in the domestic market and internationally. International sales accounted for approximately 65% and 59% of total sales in the fiscal years ending September 30, 2011 and 2010, respectively.

Direct sales include all our *Rochester Medical* ® branded sales, *Script Easy* sales and all of our other sales at Laprolan. We market our products under our *Rochester Medical*® brand through a direct sales force in the United States, the United Kingdom and the Netherlands, and through independent distributors in other international markets. As of September 30, 2011, our U.S. direct sales force consisted of thirty-four members. Internationally, we sell our *Rochester Medical*® branded products in the United Kingdom through a direct sales force of nineteen members, and in the Netherlands through a direct sales force of eight members as of September 30, 2011, respectively.

In the U.K., we also sell our *Rochester Medical* brand products and other companies' products direct to the patient 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. In fiscal 2011, the *Script-Easy* program contributed $10.4 million of net sales compared to $7.5 million in fiscal 2010, and is the vehicle where new intermittent catheter patients and *FemSoft* patients in the U.K. are driven. In the Netherlands, we have the exclusive rights to market a range of continence care, ostomy and wound and scar care products of other medical device companies. Laprolan has been an importer and distributor of medical products since 1986, and markets its products and services exclusively to healthcare institutions, physicians and specialty nurses.

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 22% of total sales in fiscal 2011, compared to 28% of total sales in fiscal 2010. Increasing our percentage of direct sales versus private label sales over time will have a positive impact on our gross margin.

Net sales for our fiscal year ended September 30, 2011 were $52.9 million, an increase of $11.5 million, or 28%, from $41.4 million in the prior fiscal year. The increase in net sales resulted from a 39% increase in direct sales for the fiscal year, while private label sales decreased 2% for the fiscal year. The increase in direct sales resulted from an increase in sales to the home care market in the United States and internationally, primarily as a result of the addition of Laprolan, as well as an increase in sales to the acute care market. Home care direct sales accounted for 86% of total direct sales for our fiscal year ended September 30, 2011.

Our five largest customers in fiscal 2011 represented approximately 30% 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.

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 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 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. 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-soft, 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.
- We currently have a national Group Purchasing Contract for urological products with Premier Purchasing Partners, L.P. through February 2013. 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.
- Similarly, we have an Innovative Technology Contract with Novation, LLC through June 2013 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). We have also been awarded a urological products contract with Broadlane Inc. through October 2014. 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. MedAssets, Inc. acquired The Broadlane Group in November 2010, and our contract with Broadlane was transitioned over to MedAssets in November 2011. MedAssets is a GPO with 180 health systems, 4,000 hospitals and 90,000 non-actue healthcare providers.
- On April 7, 2011, we completed the acquisition of the outstanding capital stock of Laprolan B.V., a corporation organized under the laws of The Netherlands and a wholly owned subsidiary of Fornix BioSciences N.V., pursuant to a Share Purchase Agreement. We paid a cash purchase price at closing of €10,474,974 (US$15,057,775, of which $60,217 was paid for the cash balance of Laprolan on January 1, 2011 and $119,433 was interest paid to Fornix from January 1, 2011 until closing). As provided in the Share Purchase Agreement, the transaction had a retroactive effective date of January 1, 2011, and the operating results of Laprolan are for our account from and after January 1, 2011. We have applied purchase accounting as of that date and have included the results of Laprolan in our financial statements beginning with the second quarter of our fiscal 2011.

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, commencing in 2010. In November 2009, the CMS issued a specific Medicare reimbursement code which covers our *FemSoft Insert*. In January 2011, the CMS notified us of their decision regarding the Medicare reimbursement fee to be used for the *FemSoft Insert* in response to our request that the pricing data used to establish the fee schedule be revised. The current Medicare fee schedule amount is based on price data that is closest to a 1986/1987 base period and is

significantly lower than the current retail price for the *FemSoft Insert.* We continue to believe that the reimbursement fee is unreasonably low, and we intend to continue to pursue a dialog with the CMS in an effort to change the reimbursement rate. We continue to believe the availability of National Healthcare System and Medicare reimbursement 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. While it is still too early to know the full potential of this product in the marketplace, management believes it can become an integral part of our product offering.

As of September 30, 2011, we had $8.7 million in cash and cash equivalents, and $26.2 million invested in marketable securities. The marketable securities primarily consist of $16.5 million invested in U.S. treasury bills, $3.2 million invested in a mutual fund and $6.5 million invested in CDs. 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 $459,000 related to the mutual fund as a result of the recent fluctuations in the credit markets impacting the current market value. We currently consider these unrealized losses to be temporary.

Our net loss for fiscal 2011 was ($1,315,000), or $0.11 per diluted share compared to a net loss of ($254,000), or $0.02 per diluted share, in fiscal 2010. The increase in net loss for fiscal 2011 compared to fiscal 2010 primarily resulted from our increased investment in sales and marketing, as well as the one-time costs associated with the acquisition of Laprolan in 2011. The objective of our three year strategic plan that we adopted at the beginning of fiscal 2011 is to double our annual overall sales during the three fiscal years of the plan, while also producing net income in an estimated range of $9 to $10 million in the third fiscal year. As part of that plan, we increased the level of investment in our sales and marketing programs in fiscal 2011 to support our direct sales growth in the U.S. and Europe through the addition of more than 30 members to our sales team. We expect the increased investment in sales and marketing programs to be funded primarily through cash generated from operations. Management believes that the ongoing strategic effort to grow our Rochester Medical direct sales through increased investment in sales and marketing programs is providing positive results. Most of the anticipated resulting acceleration in sales growth is expected to occur in fiscal years 2012 and 2013. Some quarter to quarter fluctuation in sales growth remains likely, however, through the term of the plan, primarily due to the timing of large private label orders. We will also continue to look for other strategic opportunities to increase our product line and distribution capabilities.

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, 2011, this reserve was $166,000, compared to $125,000 at September 30, 2010. 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, 2011, this allowance was $45,000 compared to $54,000 at September 30, 2010. 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 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 in that month. 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. In the rare case that price concessions are granted they are treated as a reduction in revenue.

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 post-shipment obligations to, or acceptance provisions with, our customers, including our distributors.

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 and the United Kingdom, 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. At September 30, 2011,we recorded a valuation allowance of $42,000 related to Minnesota R&D credit carryovers as we believe it is more likely than not that the deferred tax asset will not be utilized in future years. We have not recorded a valuation allowance on any other 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. We apply a fair value based impairment test on an annual basis and on an interim basis if certain triggering events or circumstances indicate that an impairment loss may have occurred by comparing the fair value of discounted cash flows for each reporting unit to its carrying value. Goodwill was $9.8 million and $4.6 million as of September 30, 2011 and 2010, respectively.

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-lived. 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 $10.3 million and $5.6 million as of September 30, 2011 and 2010, 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

Under the fair value recognition provisions of ASC 718, *Compensation-Stock Compensation*, 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, 2011 was $1.0 million after-tax ($1.5 million pre-tax). See Note 8 to our consolidated financial statements for further information regarding our stock-based compensation programs.

The estimated fair value of restricted shares is determined by the market price at the date of grant and expensed over the vesting period of four years. 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 2011.

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,		
	2011	2010	2009
Net sales	100.0%	100.0%	100.0%
Cost of sales	50.7	52.5	51.6
Gross margin	49.3	47.5	48.4
Operating expenses:			
Marketing and selling	35.8	28.6	29.7
Research and development	1.9	3.0	3.6
General and administrative	14.7	15.4	17.3
Total operating expenses	52.4	47.0	50.6
Income (loss) from operations	(3.1)	0.5	(2.2)
Other income	—	—	3.5
Interest income (expense), net	(0.6)	0.2	—
Net income (loss) before income taxes	(3.7)%	0.7%	1.3%

The following table sets forth, for the periods indicated, net sales information by market category (acute care and home care), marketing method (private label and direct sales) and distribution channel (domestic and international markets) (all dollar amounts below are in thousands):

	For the Years ended September 30,							
	2011				2010			
	US	Europe & Middle East	Rest of World	Total	US	Europe & Middle East	Rest of World	Total
Net Sales								
Acute Care — Direct	$ 2,469	$ 2,548	$ 653	$ 5,670	$ 2,322	$ 1,176	$364	$ 3,862
Home Care — Direct	7,868	27,536	350	35,754	6,397	18,925	578	25,900
Direct Total	10,337	30,084	1,003	41,424	8,719	20,101	942	29,762
Private Label	8,063	3,409	23	11,495	8,101	3,557	23	11,681
Total Net Sales	$18,400	$33,493	$1,026	$52,919	$16,820	$23,658	$965	$41,443
Direct Product Mix								
Acute Care — Direct	24%	8%	65%	14%	27%	6%	39%	13%
Home Care — Direct	76%	92%	35%	86%	73%	94%	61%	87%
Direct Total	100%	100%	100%	100%	100%	100%	100%	100%
Direct Geographic Mix								
Acute Care — Direct	6%	6%	2%	14%	8%	4%	1%	13%
Home Care — Direct	19%	66%	1%	86%	21%	64%	2%	87%
Direct Total	25%	72%	3%	100%	29%	68%	3%	100%
YOY Percentage Net Sales Growth (Decline)								
Direct	19%	50%	7%	39%	23%	33%	(9%)	28%
Private Label	0%	(4%)	0%	(2%)	10%	(14%)	35%	1%
Total Net Sales	9%	42%	6%	28%	16%	23%	(9%)	19%

Note:

Direct Sales include sales made directly to the end consumer and include all *Rochester Medical* branded sales, UK Script Easy sales and all Laprolan sales. Private label sales include our products packaged and sold by other manufacturers. Acute care refers to hospital sales. Home care refers to non-hospital sales.

Fiscal Year Ended September 30, 2011 Compared to Fiscal Year Ended September 30, 2010

Net Sales. Net sales increased 28% to $52.9 million in fiscal 2011 from $41.4 million in the prior fiscal year. The increase in net sales resulted primarily from an increase in direct sales in the Europe and Middle East ("EME") region and the U.S. for the fiscal year, offset by a slight decrease in private label sales. The increase in direct sales resulted from an increase in home care sales in both the U.S. and EME regions as well as modest increases in acute care sales in the U.S., EME and the rest of the world ("ROW"), offset by a slight decrease in home care sales in the ROW. U.S. direct sales increased by 19% over last fiscal year. Our EME direct sales increased 50% compared to last year led by a strong increase in both the U.K. and the Netherlands in acute care sales of 117% and home care sales of 46%. Private label sales were down slightly in both the U.S. and EME regions. Management believes these results demonstrate the favorable impact of our strategic decision to increase investments in direct sales and marketing programs for our *Rochester Medical* branded products, particularly for our advanced intermittent and Foley catheters, which we believe will continue to drive growth in branded sales. Additionally, beginning with the quarter ended March 31, 2011, direct sales include the sales of Laprolan B.V., our recently acquired subsidiary in the Netherlands. Total sales were partially strengthened $491,000 as a result of the change in foreign currency exchange rates in the United Kingdom as the U.S. dollar was somewhat weaker versus the pound sterling, thereby affecting sales positively given the significant volume of our *Rochester*

Medical branded product sales in the United Kingdom. Direct sales in the ROW increased slightly compared to the same period last year including an increase in acute care sales of $289,000 offset by a decrease in home care sales of $228,000. Private label sales were down $186,000 from last year. Private label sales accounted for approximately 22% of total sales in fiscal 2011 compared to 28% in the prior fiscal year. We expect private label sales as a percentage of total sales to decline over time as we focus more on growing our direct sales.

Gross Margin. Our gross margin as a percentage of net sales was 49% in fiscal 2011, compared to 48% in fiscal 2010. Increased sales of lower margin products, particularly new advanced intermittent catheters and Foley catheters, offset manufacturing efficiencies and increased sales of higher margin products, particularly male external catheters. Management expects the sale of our new advanced intermittent catheters and our Foley catheters in kit and tray configurations will continue to have a negative impact on margin until we are producing them at higher levels needed to achieve manufacturing efficiencies. However, the sale of Laprolan products and our direct sales in both the U.S. and EME should continue to have a positive impact on margin as we continue to focus on direct sales.

Marketing and Selling. As part of our three year strategic business plan through fiscal 2013, we continued to increase the investment in our sales and marketing programs, primarily through cash generated from current operations and use of available funds, to support direct 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 60% in fiscal 2011 as compared to fiscal 2010, with marketing and selling expense of approximately $19.0 million in fiscal 2011 and $11.9 million in fiscal 2010. The increase in marketing and selling expense is primarily related to $5,258,000 of compensation expenses, $1,029,000 of increased travel expenses, $441,000 of increased advertising and project costs mostly focused on our *Femsoft Insert* and our new advanced intermittent and Foley catheters, $111,000 in freight and $58,000 increase in consulting fees. Marketing and selling expense as a percentage of net sales for fiscal 2011 was 36% compared to 29% for fiscal 2010.

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 decreased from the prior year to $1,009,000 in fiscal 2011 compared to $1,235,000 in fiscal year 2010. Research and development expense as a percentage of net sales for fiscal 2011 and fiscal 2010 was 2% 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 increased to $7.8 million in 2011 from $6.4 million in fiscal 2010. The changes in general and administrative expense primarily relate to one-time costs associated with the acquisition of Laprolan, administrative expenses in Laprolan and increases of $160,000 in compensation expenses, $186,000 in depreciation, and $45,000 of travel expenses, offset by decreases of $56,000 in professional fees. General and administrative expense as a percentage of net sales for fiscal 2011 and fiscal 2010 was 15% and 15%, respectively.

Interest Income. Interest income decreased 41% to $140,000 in fiscal 2011 from $239,000 in the prior fiscal year. The decrease reflects overall lower interest rates on investments.

Interest Expense. Interest expense increased 56% to $277,000 in fiscal 2011 from $177,000 in fiscal 2010. The increase in interest expense reflects increased interest related to debt incurred to fund the acquisition of Laprolan.

Income Taxes. During the current fiscal year we generated federal net operating losses (NOLs) of approximately $3.8 million. We have U.K. NOL carry-forwards as of September 30, 2011 of approximately 1.3 million pounds sterling (approximately $2.1 million). For fiscal 2011, we recorded a valuation allowance of

$42,000 related to Minnesota R&D credit carryovers as we believe it is more likely than not that the deferred tax asset will not be utilized in future years. We have not recorded a valuation allowance on any other 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 2011, we had an effective tax rate of approximately 32% resulting primarily from foreign operations, incentive stock options and a few adjustments having an effect on the tax rate. These discrete adjustments included retroactive changes in deferred taxes as a result of a change in tax rates and recording a valuation allowance in the current year for Minnesota R&D credit carryovers. The amount of these items in comparison to our net income for the current year results in a significant effect on our effective tax rate percentage. In future periods of taxable earnings, we expect an effective tax rate in the range of 30-34%.

Net Income (Loss). For fiscal 2011, we reported a net loss of ($1,315,000) compared to a net loss of ($254,000) in fiscal 2010. The increase in net loss was primarily impacted by our increased investment in sales and marketing programs as contemplated by our three year strategic business plan and one-time costs associated with the acquisition of Laprolan.

Fiscal Year Ended September 30, 2010 Compared to Fiscal Year Ended September 30, 2009

Net Sales. Net sales increased 19% to $41.4 million in fiscal 2010 from $34.8 million in the prior fiscal year. The increase in net sales resulted primarily from an increase in direct sales in the EME region, the U.S. and private label sales offset by a slight decrease in direct sales in the ROW for the fiscal year. The increase in direct sales resulted from an increase in home care sales as well as modest increases in acute care. U.S. direct sales increased by 23% over fiscal 2009. Our EME direct sales increased 33% compared to fiscal 2009 led by a strong increase in the U.K. in acute care sales of 14% and home care sales of 34%. Private label sales were up 10% in the U.S. offset by a decrease of 14% in the EME region. Management believes these results demonstrate the favorable impact of our strategic decision to increase investments in sales and marketing programs for our *Rochester Medical* branded products, particularly for our advanced intermittent and Foley catheters. Total sales were partially strengthened (2% or $354,000) as a result of the change in foreign currency exchange rates in the United Kingdom as the U.S. dollar was somewhat weaker versus the pound sterling, thereby affecting sales positively given the significant volume of our *Rochester Medical* branded product sales in the United Kingdom. Direct sales in the ROW decreased slightly compared to the same period the prior year as a result of an increase in home sales of $105,000 offset by a decrease in acute care sales of $202,000. Private label sales were up $138,000 from the prior year and continue to fluctuate. Private label sales accounted for approximately 28% of total sales in fiscal 2010 compared to 33% in the prior fiscal year.

Gross Margin. Our gross margin as a percentage of net sales was 48% in fiscal 2010 and 2009. Increased sales of lower margin products, particularly new advanced intermittent catheters and Foley catheters, offset manufacturing efficiencies and increased sales of higher margin products, particularly male external catheters.

Marketing and Selling. For fiscal 2010, 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 15% in fiscal 2010 as compared to fiscal 2009, with marketing and selling expense of approximately $11.9 million in fiscal 2010 and $10.3 million in fiscal 2009. The increase in marketing and selling expense is primarily related to $1,015,000 of increased advertising and project costs mostly focused on our *Femsoft Insert* and our new advanced intermittent and Foley catheters, $259,000 of compensation expenses, $149,000 in freight, $120,000 of increased travel expenses and $65,000 increase in consulting fees. Marketing and selling expense as a percentage of net sales for fiscal 2010 was 29% compared to 30% for fiscal 2009.

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 remained relatively flat with the prior year at $1,235,000 in fiscal 2010 compared to $1,241,000 in the prior fiscal year. Research and development expense as a percentage of net sales for fiscal 2010 and fiscal 2009 was 3% and 4%, 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 increased to $6.4 million in 2010 from $6.0 million in fiscal 2009. The changes in general and administrative expense primarily relate to increases of $220,000 in compensation expenses, $100,000 in supplies and repairs, $90,000 in charitable contributions, $75,000 in depreciation, $45,000 of travel expenses, $43,000 of utilities expenses, and $30,000 of other expenses, offset by decreases of $210,000 in professional fees. General and administrative expense as a percentage of net sales for fiscal 2010 and fiscal 2009 was 15% and 17%, respectively.

Interest Income. Interest income decreased 16% to $239,000 in fiscal 2010 from $283,000 in the prior fiscal year. The decrease reflects overall lower interest rates on investments.

Interest Expense. Interest expense decreased 32% to $177,000 in fiscal 2010 from $259,000 in fiscal 2009. The decrease in interest expense reflects decreases in our outstanding debt that was used to partially finance our asset acquisitions in June 2006 from Mentor and Coloplast.

Income Taxes. During fiscal 2010 we utilized our remaining federal NOL carryovers, and had previously utilized all of our state NOL carryovers. We had U.K. NOL carry-forwards as of September 30, 2010 of approximately 1.3 million pounds sterling (approximately $2.0 million). For fiscal 2010, we recorded a valuation allowance of $47,000 related to Minnesota R&D credit carryovers as we believe it is more likely than not that the deferred tax asset will not be utilized in future years. We did not record a valuation allowance on any other net deferred tax assets because there was sufficient future projected income to sustain that the deferred tax assets will more likely than not be able to be utilized.

For fiscal 2010, we had an effective tax rate of approximately 194% resulting primarily from foreign operations, incentive stock options and a few discrete adjustments having an effect on the tax rate. These discrete adjustments included retroactive changes in deferred taxes as a result of a change in tax rates and recording a valuation allowance in the current year for Minnesota R&D credit carryovers. The amount of these items in comparison to our net income for fiscal year 2010 resulted in a significant effect on our effective tax rate percentage.

Net Income. For fiscal 2010, we reported a net loss of $254,000 compared to net income of $109,000 in fiscal 2009. The change in net income was primarily impacted by our increased strategic investment in sales and marketing programs, a lawsuit settlement ($1 million after payment of attorneys' fees and expenses) recorded in fiscal 2009 and the recognition of income taxes in fiscal 2010.

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 $34.9 million at September 30, 2011, compared with $35.5 million at September 30, 2010. The decrease in cash primarily resulted from cash used for capital expenditures, acquisition of Laprolan, stock repurchases, and debt repayments offset by cash provided by stock option exercises and operations. As of September 30, 2011, we had $26.2 million invested in marketable securities. The marketable securities primarily consist of $16.5 million invested in U.S. treasury bills, $3.2

million invested in a mutual fund and $6.5 million in CDs. 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 $459,000 related to the mutual fund as a result of the recent fluctuations in the credit markets impacting the current market value. We currently consider this unrealized loss to be temporary.

We generated a net $2.6 million of cash in operating activities during the year compared with $3.1 million for the same period last year, with the primary difference being decreased levels of accounts receivable offset by increased levels of inventory and prepaid asset balances at the end of fiscal 2011. Cash flow provided by operating activities in 2011 was comprised of net loss of $1,315,000 increased by a decrease in net working capital components and increased by net non-cash charges of $4.0 million, including depreciation and amortization of $2.5 million and stock-based compensation of $1.5 million. Significant working capital changes are as follows:

- a $653,000 decrease in accounts receivable reflecting timing of cash collections over prior year,
- a $323,000 increase in inventory levels,
- a $834,000 increase in deferred income taxes,
- a $519,000 increase in prepaid expenses and other current assets,
- a $478,000 increase in accounts payable reflecting timing of payments, and
- a $614,000 increase in income taxes payable.

During fiscal 2011, our working capital position, excluding cash and marketable securities, decreased by $12.8 million as a result of short term borrowings used to fund the acquisition of Laprolan. Accounts receivable balances decreased $653,000 during the fiscal year primarily due to timing of collections at the end of the fourth quarter. Inventories as of September 30, 2011 increased $323,000 over fiscal 2010. Changes in other asset and liability balances related to timing differences.

Investing activities, primarily capital expenditures and the acquisition of Laprolan offset by the sale of marketable securities, used net cash of $11.7 million in fiscal 2011.

Financing activities, primarily proceeds from short term debt offset by long term debt payments and share repurchases, provided net cash of $13.4 million in fiscal 2011.

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 was non-interest bearing, payable and due in five equal installments of $1,068,000 payable annually on June 2. We discounted the note at 6.90%. The final payment of $1,068,000 was made in May 2011.

In December 2010, we entered into a credit facility with RBC Wealth Management. The credit facility consists of a revolving line of credit of up to $25,000,000 with interest accruing monthly at a variable rate currently at 1.375%. In conjunction with the closing of the Laprolan acquisition, on April 7, 2011, we drew down $15,057,775 from the line of credit. As of September 30, 2011, we had an outstanding balance under the revolving line of credit of $17,862,185.

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 and financial conditions and to 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, 2011:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Contractual Obligations					
Short term debt, including interest	$17,962,664	$17,962,664	—	—	—
Unrecognized tax benefits under FIN 48(1)	42,089	—	42,089	—	—
Operating leases	944,524	515,028	429,496	—	—
Purchase obligations (general operating)	3,187,123	3,187,123	—	—	—
Total Contractual Obligations	$22,136,400	$21,664,815	$471,585	$—	$—

(1) See Item 8 of Part II of this Form 10-K, "Financial Statements and Supplementary Data—Note 9—Income Taxes."

Off-Balance Sheet Arrangements

As of September 30, 2011, 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 January 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2010-06, " *Improving Disclosures about Fair Value Measurements,*" that requires entities to make new disclosures about recurring or nonrecurring fair-value measurements and provides clarification of existing disclosure requirements. For assets and liabilities that are measured at fair value on a recurring basis, the ASU requires disclosure of significant transfers between Levels 1 and 2, and transfers into and out of Level 3 of the fair value hierarchy and the reasons for those transfers. Significant transfers into each level must be disclosed and discussed separately from transfers out of each level. Significance is judged with respect to earnings, total assets, total liabilities or total equity. An accounting policy must be determined and disclosed as to when transfers between levels are recognized: (1) actual date, (2) beginning of period or (3) end of period. The ASU amends the reconciliation of the beginning and ending balances of Level 3 recurring fair value measurements to present

information about purchases, sales, issuances and settlements on a gross basis rather than as a net number. The ASU amends ASC 820 to require fair value measurement disclosures for each class of assets and liabilities and clarifies that a description of the valuation technique and inputs used to measure fair value is required for both recurring and nonrecurring fair value measurements. This standard became effective for our fiscal year ending September 30, 2010, except for the requirement to provide the Level activity of purchases, sales, issuances and settlement on a gross basis, which became effective beginning in the first quarter of fiscal year 2011. Since this standard impacts disclosure requirements only, its adoption will not have a material impact on our consolidated financial statements.

In December 2010, the FASB issued ASU No. 2010-29, *"Disclosures of Supplementary Pro Forma Information for Business Combinations."* This ASU requires a public entity to disclose pro forma information for business combinations that occurred in the current reporting period. The disclosures include pro forma revenue and earnings of the combined entity for the current reporting period as though the acquisition date for all business combinations that occurred during the year had been as of the beginning of the annual reporting period. If comparative financial statements are presented, the pro forma revenue and earnings of the combined entity for the comparable prior reporting period should be reported as though the acquisition date for all business combinations that occurred during the current year had been as of the beginning of the comparable prior annual reporting period. ASU No. 2010-29 affects any public entity as defined by ASC 805 that enters into business combinations that are material on an individual or aggregate basis. ASU No. 2010-29 is effective prospectively for 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, 2010. Early adoption is permitted and we adopted ASU No. 2010-29 in the second fiscal quarter of 2011. The adoption of this standard did not have a material impact on our consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *"Presentation of Comprehensive Income."* This ASU eliminates the current option to report other comprehensive income and its components in the statement of changes in equity and requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In addition, it requires entities to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income in the statements where the components of net income and the components of other comprehensive income are presented. ASU No. 2011-05 will become effective for public entities for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The standard will become effective for us in January 2012. We are currently evaluating the impact of ASU No. 2011-05 on our consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, *"Testing Goodwill for Impairment."* This ASU will allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. Under these amendments, an entity would not be required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The amendments include a number of events and circumstances for an entity to consider in conducting the qualitative assessment. ASU No. 2011-08 will become effective for public entities for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The standard will become effective for us in January 2012. We are currently evaluating the impact of ASU No. 2011-05 on our consolidated financial statements.

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 successfully establishing our separate *Rochester Medical* brand identity;
- the uncertainty of timing of revenues from private label sales (particularly with respect to international customers);
- the uncertainty of successfully growing our international operations;
- the risks associated with operating an international business, including the impact of foreign currency exchange rate fluctuations;
- the uncertainty of gaining new strategic relationships;
- the securing of Group Purchasing Organization contract participation;
- the uncertainty of gaining significant sales from secured GPO contracts;
- FDA and other regulatory review and response times;
- 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, 2011. 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 concluded that the company maintained effective internal control over financial reporting as of September 30, 2011. This assessment did not include the internal controls related to the acquisition of Laprolan B.V. from Fornix BioSciences N.V. that occurred on April 7, 2011 with a retroactive effective date to January 1, 2011. Total assets and sales related to this acquisition represent 19.1% and 13.1%, respectively, of the related consolidated financial statement amounts as of and for the year ended September 30, 2011. Companies are allowed to exclude acquisitions from their assessment of internal control over financial reporting during the first year of an acquisition under guidelines established by the SEC.

Our independent auditor has audited our consolidated financial statements and the effectiveness of internal controls over financial reporting as of September 30, 2011 as stated in their reports on pages 41 and 42.

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, British pounds and euros. 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 variable rate currently at 1.375%. As of September 30, 2011 we had an outstanding balance of $17,862,185 under the revolving line of credit.

In future periods, we believe a greater portion of our revenues could be denominated in currencies other than the U.S. dollar, thereby increasing our exposure to exchange rate gains and losses on non-United States currency transactions. Sales through our subsidiary, Rochester Medical, Ltd., are denominated in pound sterling, and fluctuations in the rate of exchange between the U.S. dollar and the pound sterling could adversely affect our financial results. Similarly, sales through our subsidiary, Laprolan B.V., are denominated in euros, and fluctuations in the rate of exchange between the U.S. dollar and the euro 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, 2011, 2010 and 2009

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 subsidiaries (collectively, the "Company") as of September 30, 2011 and 2010 and the related consolidated statements of operations, shareholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended September 30, 2011. 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 statement 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 subsidiaries as of September 30, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2011 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, 2011, 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 9, 2011 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
December 9, 2011

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Rochester Medical Corporation

We have audited Rochester Medical Corporation's (a Minnesota corporation) internal control over financial reporting as of September 30, 2011, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Rochester Medical Corporation's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on Rochester Medical Corporation'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, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, 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.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls related to the acquisition of Laprolan B.V. included in the September 30, 2011 consolidated financial statements of Rochester Medical Corporation and constituted 19.1% and 22.6% of total and net assets, respectively, as of September 30, 2011 and 13.1% of revenues for the year then ended. Our audit of internal control over financial reporting of Rochester Medical Corporation also did not include an evaluation of the internal control over financial reporting of Laprolan B.V.

In our opinion, Rochester Medical Corporation maintained, in all material respects, effective internal control over financial reporting as of September 30, 2011, 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 sheet of Rochester Medical Corporation as of September 30, 2011 and 2010, and the related consolidated statements of operations, shareholders' equity and comprehensive income (loss), and cash flows and financial statement schedule for each of the three years in the period ended September 30, 2011, and our report dated December 9, 2011 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
December 9, 2011

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS

	September 30, 2011	September 30, 2010
Assets:		
Current assets:		
Cash and cash equivalents	$ 8,722,935	$ 4,545,907
Marketable securities	26,182,308	30,967,007
Accounts receivable, less allowance for doubtful accounts ($44,595 – 2011; $54,048 - 2010)	8,644,332	7,858,540
Inventories	11,278,694	9,240,291
Prepaid expenses and other current assets	1,361,259	846,899
Deferred income tax asset	1,618,495	872,849
Total current assets	57,808,023	54,331,493
Property, plant and equipment:		
Land	1,115,883	695,872
Buildings	9,455,840	7,301,551
Equipment and fixtures	19,531,006	18,543,813
	30,102,729	26,541,236
Less accumulated depreciation	(18,050,044)	(16,523,997)
Total property, plant and equipment	12,052,685	10,017,239
Deferred income tax asset	1,242,010	1,175,052
Goodwill	9,764,075	4,561,781
Intangible assets, less accumulated amortization ($3,682,633 - 2011; $2,747,745 - 2010)	10,061,655	5,351,620
Patents, less accumulated amortization ($1,328,486 – 2011; $1,268,907 - 2010)	211,016	229,106
Total assets	$ 91,139,464	$ 75,666,291
Liabilities and Shareholders' Equity:		
Current liabilities:		
Accounts payable	$ 2,773,398	$ 2,016,058
Accrued compensation	1,460,726	1,458,652
Accrued expenses	1,500,544	610,570
Current maturities of debt	17,862,185	2,641,233
Total current liabilities	23,596,853	6,726,513
Long-term liabilities	1,565,764	46,327
Shareholders' equity:		
Common stock, no par value:		
Authorized shares — 40,000,000		
Issued and outstanding shares: (12,141,817 – 2011; 12,072,452 - 2010)	56,829,350	57,200,531
Retained earnings	13,263,374	14,578,678
Accumulated other comprehensive loss	(4,115,877)	(2,885,758)
Total shareholders' equity	65,976,847	68,893,451
Total liabilities and shareholders' equity	$ 91,139,464	$ 75,666,291

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

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Fiscal Years Ended September 30,		
	2011	2010	2009
Net sales	$52,918,875	$41,442,680	$34,798,829
Cost of sales	26,821,427	21,739,014	17,973,314
Gross profit	26,097,448	19,703,666	16,825,515
Operating expenses:			
Marketing and selling	18,966,887	11,868,737	10,327,396
Research and development	1,008,767	1,235,367	1,241,095
General and administrative	7,799,210	6,391,003	6,006,906
Total operating expenses	27,774,864	19,495,107	17,575,397
Income (loss) from operations	(1,677,416)	208,559	(749,882)
Other income (expense):			
Interest income	139,859	239,171	283,195
Other income (expense)	(123,901)	—	1,200,442
Interest expense	(277,008)	(177,401)	(259,341)
Total other income (loss)	(261,050)	61,770	1,224,296
Net income (loss) before income taxes	(1,938,466)	270,329	474,414
Income tax benefit (expense)	623,162	(523,864)	(365,742)
Net income (loss)	$ (1,315,304)	$ (253,535)	$ 108,672
Net income (loss) per common share — basic	$ (.11)	$ (.02)	$ .01
Net income (loss) per common share — diluted	$ (.11)	$ (.02)	$ .01
Weighted average number of common shares outstanding — basic	12,217,900	12,181,549	12,045,313
Weighted average number of common shares outstanding — diluted	12,217,900	12,181,549	12,639,853

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, 2008	11,936,586	54,223,669	14,723,541	(1,248,681)	67,698,529
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
Net loss for the year	—	—	(253,535)	—	(253,535)
Foreign currency translation adjustment	—	—	—	(117,457)	(117,457)
Tax effect on unrealized loss on securities	—	—	—	(46,814)	(46,814)
Unrealized gain on available-for-sale securities	—	—	—	131,685	131,685
Subtotal-comprehensive loss					(286,121)
Tax benefit of stock options exercised	—	39,970	—	—	39,970
Stock based compensation	—	1,481,102	—	—	1,481,102
Common stock repurchased	(132,915)	(1,202,339)	—	—	(1,202,339)
Stock option exercises	15,000	40,942	—	—	40,942
Balance at September 30, 2010	12,072,452	$57,200,531	$14,578,678	$(2,885,758)	$68,893,451
Net loss for the year	—	—	(1,315,304)	—	(1,315,304)
Foreign currency translation adjustment	—	—	—	(1,201,334)	(1,201,334)
Tax effect on unrealized loss on securities	—	—	—	17,382	17,382
Unrealized loss on available-for-sale securities	—	—	—	(46,167)	(46,167)
Subtotal-comprehensive loss					(2,545,423)
Stock based compensation	—	1,495,773	—	—	1,495,773
Common stock repurchased	(284,585)	(2,513,871)	—	—	(2,513,871)
Stock option exercises	353,950	646,917	—	—	646,917
Balance at September 30, 2011	12,141,817	$56,829,350	$13,263,374	$(4,115,877)	$65,976,847

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

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Fiscal Years Ended September 30,		
	2011	2010	2009
Operating Activities:			
Net income (loss)	$ (1,315,304)	$ (253,535)	$ 108,672
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	1,538,102	1,407,963	1,234,081
Amortization	978,953	694,925	692,756
Stock based compensation	1,495,773	1,481,102	1,330,220
Deferred income taxes	(834,412)	(172,627)	196,545
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable	652,640	(1,481,287)	(657,793)
Inventories	(323,136)	409,967	(1,101,735)
Prepaid expenses and other current assets	(519,003)	228,520	(62,859)
Accounts payable	478,189	269,679	(320,632)
Income tax payable	614,218	265,874	(60,034)
Other current liabilities	(120,912)	267,041	325,055
Net cash provided by operating activities	2,645,108	3,117,622	1,684,276
Investing Activities:			
Purchase of property, plant and equipment	(1,756,285)	(1,763,869)	(1,171,788)
Business acquisition, net of cash acquired	(15,057,816)	—	—
Patents, intangibles and goodwill	346,571	(65,882)	(57,685)
Purchases of marketable securities	(46,363,183)	(66,622,304)	(55,358,876)
Sales and maturities of marketable securities	51,101,714	65,683,722	53,853,269
Net cash used in investing activities	(11,728,999)	(2,768,333)	(2,735,080)
Financing Activities:			
Proceeds from short-term debt	17,864,367	—	—
Increase in short-term debt	—	600,000	2,000,000
Payments on long-term debt	(2,643,415)	(1,765,124)	(3,940,120)
Excess tax benefit from exercises of stock options	—	39,979	562,308
Repurchase of common stock	(2,513,871)	(1,202,339)	(1,058,041)
Proceeds from issuance of common stock	646,917	40,942	1,782,700
Net cash provided by (used in) financing activities	13,353,998	(2,286,542)	(653,153)
Effect of exchange rate on cash and cash equivalents	(93,079)	117,576	(438,459)
Increase (decrease) in cash and cash equivalents	4,177,028	(1,819,677)	(2,142,416)
Cash and cash equivalents at beginning of year	4,545,907	6,365,584	8,508,000
Cash and cash equivalents at end of year	$ 8,722,935	$ 4,545,907	$ 6,365,584
Supplemental Cash Flow Information:			
Cash paid for interest	$ 73,907	$ 109,779	$ 443,791
Cash paid for income taxes	85,602	264,743	313,640

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 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 also sells certain ostomy and wound and scar care products and other brands of urological products into the European marketplace.

The Company's fiscal year end is September 30. The accompanying financial statements include the accounts of Rochester Medical Corporation, Rochester Medical Limited, its wholly owned subsidiary in the United Kingdom, and Laprolan B.V., its wholly owned subsidiary in the Netherlands, 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, valuations used in purchase of Laprolan, deferred income taxes 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 subsidiaries. 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 $7.0 million and $4.1 million at September 30, 2011 and 2010 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, 2011, the Company has $26.2 million invested in high quality, investment grade debt securities, primarily consisting of $16.5 million invested in U.S. treasury bills, $3.2 million invested in a mutual fund and $6.5 million invested in CDs. At September 30, 2010, the Company's marketable securities included $31.0 million invested in high quality, investment grade debt securities, consisting of $25.7 million invested in U.S. treasury bills, $3.1 million invested in a mutual fund and $2.2 million invested in CDs. The Company reported an unrealized loss of $459,000 related to the mutual fund investment as of September 30, 2011; the unrealized loss was $413,000 at September 30, 2010. The Company currently considers this unrealized loss to be temporary.

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, 2011	$26,641,059	$(458,751)	$26,182,308
September 30, 2010	$31,379,590	$(412,583)	$30,967,007

Realized gains and 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.

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.

Intangible Assets

Intangible assets consist primarily of purchased trademarks, a supply agreement, and customer relationships and are amortized using the straight-line method, as appropriate, over their estimated useful lives, ranging from 5 to 20 years. The Company reviews these intangible assets for impairment as changes in circumstance or the occurrence of triggering events suggest the remaining value may not be recoverable. No impairment loss was recognized in the fiscal years ended September 30, 2011, 2010 and 2009.

Goodwill

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. Goodwill is also not amortizable for tax purposes. 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 has $4,148,000 of goodwill carrying value as of September 30, 2011 resulting from its acquisition in the U.K. of Rochester Medical Limited in 2006 and $5,616,000 of goodwill carrying value resulting from its acquisition in the Netherlands of Laprolan B.V. in 2011. The Company tests annually for impairment of the asset, currently on June 2nd of each fiscal year for the goodwill associated with the Company's 2006 UK acquisition and for the goodwill related to the 2011 Netherlands acquisition, or more frequently if the occurrence of triggering events and circumstances indicate that the asset might be impaired. The Company applies a fair value based impairment test on an annual basis and on an interim basis if certain triggering events or circumstances indicate that an impairment loss may have occurred by comparing the fair value of discounted cash flows for each reporting unit to its carrying value. The Company performed its most recent annual goodwill impairment testing of the goodwill at June 2, 2011, and concluded that the goodwill was not impaired. No impairment loss was recognized in the fiscal years ended September 30, 2011, 2010 and 2009. The increase in value of goodwill as of September 30, 2011 is entirely related to the goodwill recorded during the purchase of Laprolan, offset by a decrease due to a change in foreign currency exchange rates in the United Kingdom and a final purchase price adjustment per the Mentor/Coloplast purchase agreement.

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, 2011, 2010 and 2009.

Foreign Currency Translation

The financial statements of the Company's non-U.S. subsidiaries are translated into U.S. dollars in accordance with ASC 830, *Foreign Currency Matters*. Under ASC 830, if the assets and liabilities of certain non-U.S. functional currencies are other than the U.S. dollar they 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. 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 its 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 in that month. 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. In the rare case that price concessions are granted they are treated as a reduction in revenue.

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 post-shipment obligations to, or acceptance provisions with, its customers, including its distributors.

Shipping and Handling

Shipping and handling billed to customers is recorded as revenue. Shipping and handling costs are recorded within cost of goods sold for the parent company and recorded as marketing and selling costs for each of its subsidiaries.

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. For fiscal 2011, the Company recorded a valuation allowance of $42,000 related to Minnesota R&D credit carryovers as the Company believes it is more likely than not that the deferred tax asset will not be utilized in future years. The Company has not recorded a valuation allowance on any other 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 realized.

It is the Company's practice to recognize penalties and/or interest to income tax matters in income tax expenses. As of September 30, 2011, 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, the Netherlands 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. The Company reduced its reserves in accordance with ASC 740, *Income Taxes* for unrecognized tax benefits as a result of the settlement reached with the IRS.

Advertising Costs

The Company incurred advertising expenses of $1,370,000, $1,600,000 and $929,000 for the years ended September 30, 2011, 2010 and 2009, 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 $1,496,000, $1,481,000 and $1,330,000 ($969,000, $959,000 and $878,000 net of tax) of related stock-based compensation expense for the years ended September 30, 2011, 2010 and 2009, respectively.

Net Income (Loss) Per Share

Net income (loss) per common share is calculated in accordance with ASC 260, *Earnings Per Share*. The Company's basic net income (loss) per common share is computed by dividing net income (loss) 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 (loss) per share calculation is as follows:

	Year Ended September 30,		
	2011	2010	2009
Numerator:			
Net income (loss)	$(1,315,304)	$ (253,535)	$ 108,672
Denominator:			
Denominator for basic net income per common share — weighted average shares outstanding	12,217,900	12,181,549	12,045,313
Effect of dilutive stock options	—	—	594,540
Denominator for diluted net income per common share — weighted average shares outstanding	12,217,900	12,181,549	12,639,853

Employee stock options of 230,000 for fiscal year 2009 have been excluded from the diluted net income (loss) per common share calculations because their exercise prices were greater than the average market price of the Company's common stock.

For the years ended September 30, 2011 and 2010, 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 net loss, as they are antidilutive. Average shares outstanding for diluted earnings per share does not include options to purchase 64,645 and 706,845 shares of common stock for the fiscal years 2011 and 2010, respectively, as their effect would have been antidilutive.

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.

Comprehensive Income

The Company computes comprehensive income (loss) in accordance with Financial Accounting Standards Board (FASB) ASC 220, *Comprehensive Income,* (formerly SFAS No. 130, *Reporting Comprehensive Income*). FASB ASC 220 establishes standards for the reporting and display of comprehensive income (loss) and its components in financial statements. Other comprehensive income (loss), as defined, includes all changes in equity during a period from non-owner sources, such as unrealized gains and losses on available-for-sale securities and foreign currency translation. Total accumulated other comprehensive loss as of fiscal year-end 2011 and 2010 was as follows:

	2011	2010
Unrealized (loss) on available-for-sale securities	$ (458,751)	$ (412,583)
Cumulative foreign currency translation	(3,657,126)	(2,473,175)
Accumulated other comprehensive loss	$(4,115,877)	$(2,885,758)

New Accounting Pronouncements

In January 2010, the FASB issued Accounting Standards Update (ASU) No. 2010-06, " *Improving Disclosures about Fair Value Measurements,"* that requires entities to make new disclosures about recurring or nonrecurring fair-value measurements and provides clarification of existing disclosure requirements. For assets and liabilities that are measured at fair value on a recurring basis, the ASU requires disclosure of significant transfers between Levels 1 and 2, and transfers into and out of Level 3 of the fair value hierarchy and the reasons for those transfers. Significant transfers into each level must be disclosed and discussed separately from transfers out of each level. Significance is judged with respect to earnings, total assets, total liabilities or total equity. An accounting policy must be determined and disclosed as to when transfers between levels are recognized: (1) actual date, (2) beginning of period or (3) end of period. The ASU amends the reconciliation of the beginning and ending balances of Level 3 recurring fair value measurements to present information about purchases, sales, issuances and settlements on a gross basis rather than as a net number. The ASU amends ASC 820 to require fair value measurement disclosures for each class of assets and liabilities and clarifies that a description of the valuation technique and inputs used to measure fair value is required for both recurring and nonrecurring fair value measurements. This standard became effective for the Company's fiscal year ending September 30, 2010, except for the requirement to provide the Level activity of purchases, sales, issuances and settlement on a gross basis, which became effective beginning in the first quarter of fiscal year 2011. Since this standard impacts disclosure requirements only, its adoption will not have a material impact on the Company's consolidated financial statements.

In December 2010, the FASB issued ASU No. 2010-29, *"Disclosures of Supplementary Pro Forma Information for Business Combinations."* This ASU requires a public entity to disclose pro forma information for business combinations that occurred in the current reporting period. The disclosures include pro forma revenue and earnings of the combined entity for the current reporting period as though the acquisition date for all business combinations that occurred during the year had been as of the beginning of the annual reporting period. If comparative financial statements are presented, the pro forma revenue and earnings of the combined entity for the comparable prior reporting period should be reported as though the acquisition date for all business combinations that occurred during the current year had been as of the beginning of the comparable prior annual reporting period. ASU No. 2010-29 affects any public entity as defined by ASC 805 that enters into business combinations that are material on an individual or aggregate basis. ASU No. 2010-29 is effective prospectively for 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, 2010. Early adoption is permitted and the Company adopted ASU No. 2010-29 in the second fiscal quarter of 2011. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, *"Presentation of Comprehensive Income."* This ASU eliminates the current option to report other comprehensive income and its components in the statement of changes in equity and requires that all non-owner changes in stockholders' equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In addition, it requires entities to present on the face of the financial statements reclassification adjustments for items that are reclassified from other comprehensive income to net income in the statements where the components of net income and the components of other comprehensive income are presented. ASU No. 2011-05 will become effective for public entities for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The standard will become effective for the Company in January 2012. The Company is currently evaluating the impact of ASU No. 2011-05 on its consolidated financial statements.

In September 2011, the FASB issued ASU No. 2011-08, *"Testing Goodwill for Impairment."* This ASU will allow an entity to first assess qualitative factors to determine whether it is necessary to perform the two-step quantitative goodwill impairment test. Under these amendments, an entity would not be required to calculate the fair value of a reporting unit unless the entity determines, based on a qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The amendments include a number of events and

circumstances for an entity to consider in conducting the qualitative assessment. ASU No. 2011-08 will become effective for public entities for fiscal years, and interim periods within those years, beginning after December 15, 2011, with early adoption permitted. The standard will become effective for the Company in January 2012. The Company is currently evaluating the impact of ASU No. 2011-05 on its consolidated financial statements.

3. Acquisition of Laprolan B.V. from Fornix BioSciences N.V.

On April 7, 2011, the Company completed the acquisition of the outstanding capital stock of Laprolan B.V., a corporation organized under the laws of the Netherlands and a wholly owned subsidiary of Fornix BioSciences N.V., pursuant to a Share Purchase Agreement dated as of January 12, 2011 (the "Purchase Agreement"). As provided in the Purchase Agreement, the transaction has a retroactive effective date of January 1, 2011, and the operating results of Laprolan are for the account of the Company from and after January 1, 2011. The Company is applying purchase accounting as of that date and has included the results of Laprolan in its financial statements beginning in its second fiscal quarter. At closing, the Company paid to Fornix €10,474,974 (US$15,057,775, of which $60,217 was paid for the cash balance of Laprolan on January 1, 2011 and $119,433 was interest from January 1, 2011 until closing).

The following table summarizes the estimated fair values of the assets and liabilities acquired at the date of acquisition. Included in the intangible assets acquired is approximately $5,602,000 of goodwill and $5,612,000 of finite –lived intangibles. As the Company completes its post-closing review and valuation of the acquisition, the allocation of the purchase price may change. Any change to the preliminary values of finite-lived intangibles and property and equipment could result in more or less amortization expense. The Company made one post-closing adjustment in the fourth quarter increasing inventory by approximately $76,000 and reducing goodwill.

Current assets	$ 3,212,000
Property and equipment	1,831,000
Intangible assets	11,214,000
Total assets acquired	$16,257,000
Current liabilities	$ 824,000
Long term liabilities	1,546,000
Total liabilities assumed	$ 2,370,000

The pro forma unaudited results of operations for the years ended September 30, 2011 and 2010, assuming consummation of the purchase of Laprolan B.V. as of October 1, 2009, are as follow (in thousands):

	Year Ended September 30,	
	2011	2010
Net sales	$55,633	$52,767
Net income (loss)	(159)	2,356
Per share data:		
Basic earnings (loss)	$ (0.01)	$ 0.19
Diluted earnings (loss)	$ (0.01)	$ 0.18

In the table above, $725,000 has been added back to net income (loss) for the year ended September 30, 2011 for one-time merger and acquisition costs and $45,000 has been added back to net income (loss) for the year ended September 30, 2011 related to a short term accounting and IT support contract.

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

4. 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.

5. Inventories

Inventories are summarized as follows:

	September 30,	
	2011	2010
Raw materials	$ 1,548,095	$1,756,313
Work-in-process	3,598,623	3,233,644
Finished goods	6,298,415	4,375,798
Reserve for inventory obsolescence	(166,439)	(125,464)
Totals	$11,278,694	$9,240,291

6. Intangible Assets

Intangible assets were as follows:

		September 30, 2011			September 30, 2010		
	Estimated Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net Value	Gross Carrying Amount	Accumulated Amortization	Net Value
Trademarks	8 to 15	$ 5,958,480	$2,187,663	$ 3,770,817	$5,423,000	$1,755,762	$3,667,238
Supply agreement	5 to 6.5	767,870	628,357	139,513	634,000	549,470	84,530
Customer relationships	15 to 20	7,017,938	866,613	6,151,325	2,042,365	442,513	1,599,852
Totals		$13,744,288	$3,682,633	$10,061,655	$8,099,365	$2,747,745	$5,351,620

Amortization expense related to these assets was as follows:

Year ended September 30, 2011	$934,890
Year ended September 30, 2010	633,335
Year ended September 30, 2009	632,661

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

2012	$872,000
2013	850,000
2014	819,000
2015	757,000
2016	757,000

7. Leases

The Company leases many of its automobiles for its sales staff in the United States, the United Kingdom and the Netherlands for various terms under long-term, non-cancelable operating lease agreements. The leases expire at various dates through 2014. 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 $724,000, $378,000 and $312,000 during fiscal 2011, 2010 and 2009, respectively.

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

2012	$515,000
2013	323,000
2014	106,000

8. Shareholders' Equity

Stock Options and Restricted Stock

The Rochester Medical Corporation 2001 Stock Incentive Plan authorized 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. As of January 28, 2010, no new awards may be granted under the 2001 Stock Incentive Plan. As of September 30, 2011, there were 1,155,750 options outstanding under this plan.

On January 28, 2010, the Company's shareholders approved the Rochester Medical Corporation 2010 Stock Incentive Plan. The 2010 Stock Incentive Plan authorizes the issuance of up to 1,000,000 shares of common stock pursuant to grants of incentive stock options, non-incentive stock options, stock appreciation rights, restricted stock, restricted stock units, dividend equivalents, performance awards, stock awards, and other stock-based awards. Per the terms of the 2010 Stock Incentive Plan, awards may be granted with a term no longer than ten years. The vesting schedule and other terms of the awards granted under the 2010 Stock Incentive Plan will be determined by the Compensation Committee of the Board of Directors at the time of the grant.

Stock-based awards activity for the year ended September 30, 2011 is summarized as follows:

	Shares Reserved For Grant	Options and Restricted Shares Outstanding	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contract Life
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
2010 Option Plan approved	1,000,000	—		
Options granted	(203,000)	203,000	12.27	
Options exercised	—	(15,000)	2.73	
Options canceled	7,500	(7,500)	11.78	
Options expired	2,500	(2,500)	11.78	
2001 Plan — options canceled and not reissuable	(244,500)	—	9.76	
Balance as of September 30, 2010	797,000	1,672,700	7.83	5.31 years
Options granted	(230,000)	230,000	10.72	
Granted — restricted shares	(40,000)	40,000	—	
Options exercised	—	(353,950)	1.83	
Balance as of September 30, 2011	527,000	1,588,750	$ 9.39	5.83 years
Outstanding options exercisable at end of period		1,160,625	$ 8.68	4.89 years

As of September 30, 2011, there were 527,000 shares that remained available for issuance under the 2010 Stock Incentive Plan, and there were 433,000 options and 40,000 shares of restricted stock outstanding under this plan. The number of stock options exercisable at September 30, 2011, 2010 and 2009 was 1,160,625, 1,227,700 and 1,062,075 at a weighted average exercise price of $8.68, $6.79 and $6.04 per share, respectively.

At September 30, 2011, the aggregate intrinsic value of options outstanding was $1,463,876, and the aggregate intrinsic value of options exercisable was $1,463,876. Total intrinsic value of options exercised was $2,823,076 for the year ended September 30, 2011.

The Company measures stock-based compensation cost at the grant date base on the fair value of the award and recognizes the compensation expense over the requisite service period, which is generally the vesting period. As of September 30, 2011, $1,641,657 of unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately fifteen months.

The weighted average fair value of options granted in 2011, 2010 and 2009 was $6.29, $7.14 and $6.70 per share, respectively. The exercise price of options outstanding at September 30, 2011 ranged from $2.17 to $18.02 per share as summarized in the following table:

Range of Exercise Prices	Number Outstanding at 9/30/11	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price Per Share - Total Options Outstanding	Number Exercisable at 9/30/11	Weighted Average Exercise Price Per Share - Options Exercisable
$0.00 - $5.00	357,250	2.2 years	$ 4.20	357,250	$ 4.20
$5.01 - $10.00	150,000	4.4 years	5.91	150,000	5.91
$10.01 - $15.00	1,076,500	7.2 years	11.56	648,375	11.72
$15.01 - $20.00	5,000	5.5 years	18.02	5,000	18.02
	1,588,750	5.8 years	$ 9.39	1,160,625	$ 8.68

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:

	2011	2010
Dividend yield	0%	0%
Expected volatility	47%	48%
Risk-free interest rate	3.42%	3.15%
Expected holding period (in years)	8.74	8.46
Weighted-average grant-date fair value	$6.29	$7.14

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.

The estimated fair value of the restricted shares was determined by the market price at the date grant and expensed over a period of four years.

9. 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,	
	2011	2010
Deferred income tax assets:		
Allowance for doubtful accounts	$ 15,000	$ 18,000
Inventory reserves	57,000	42,000
Inventory capitalization	450,000	481,000
Accrued expenses	94,000	98,000
Nonqualified option expense	1,648,000	1,217,000
Restricted stock expense	17,000	147,000
Capital loss carryforward	39,000	37,000
Charitable contributions	58,000	41,000
Research and development credits	71,000	47,000
Net operating loss	1,095,000	545,000
ASC 320 unrealized loss	202,000	147,000
Valuation allowance	(42,000)	(47,000)
Total income tax deferred assets	3,704,000	2,773,000
Deferred income tax liability:		
Depreciation and amortization	2,353,000	723,000
Net deferred income tax assets	$1,351,000	$2,050,000

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

	September 30,	
	2011	2010
Current assets	$ 1,618,495	$ 872,849
Noncurrent assets	1,242,010	1,175,052
Noncurrent liabilities	(1,509,862)	—
	$ 1,350,643	$2,047,901

Of the deferred tax assets listed above, approximately $120,000 of foreign net operating losses is related to other comprehensive income and will not impact the tax provision when utilized.

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. For fiscal 2011, the Company recorded a valuation allowance of $42,000 related to Minnesota R&D credit carryovers as the Company believes it is more likely than not that the deferred tax asset will not be utilized in future years. The Company has not recorded a valuation allowance on any other 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 realized.

The income (loss) before taxes and the provision (benefit) for taxes for the years ended September 30, 2011, 2010, and 2009 consist of the following:

	September 30,		
	2011	2010	2009
Income (loss) before taxes:			
U.S.	$(3,565,971)	$ 584,963	$1,155,518
Non-U.S.	1,627,505	(314,634)	(681,104)
Total income (loss) before taxes	(1,938,466)	270,329	474,414
Provision (benefit) for taxes:			
U.S.			
Current tax expense (benefit)	(142,766)	551,779	622,512
Deferred tax expense (benefit)	(946,530)	609	(163,393)
Total U.S.	(1,089,296)	552,388	459,119
Non-U.S.			
Current tax expense	425,820	—	1,857
Deferred tax expense (benefit)	40,314	(28,524)	(95,234)
Total Non-U.S.	466,134	(28,524)	(93,377)
Total provision (benefit) for taxes	$ (623,162)	$ 523,864	$ 365,742

The reconciliation between the statutory federal income tax rate and the effective income tax rate for the years ended September 30, 2011, 2010 and 2009 is as follows:

	2011	2010	2009
Statutory federal income tax rate	34%	34%	34%
Increase (decrease) in taxes resulting from:			
State taxes	3	4	6
Foreign taxes	11	31	29
Meals and entertainment	(2)	6	9
Acquisition costs	(9)	—	—
Incentive stock options	(9)	66	28
Change in valuation allowance and utilization of net operating loss carryforward	—	17	—
R&D credits	1	(15)	(38)
Return to provision & true up adjustments	(2)	46	—
Change in reserves	1	(4)	(2)
Rate adjustment on deferred taxes	7	18	—
DPAD	—	(10)	8
Other	(3)	1	3
Effective income tax rate	32%	194%	77%

On October 1, 2007, the Company adopted amendments to ASC 740, *Income Taxes*, 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 under ASC 740 for unrecognized tax benefits. As of September 30, 2011, 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, 2011, 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, 2011, the Company did not have a material amount of accrued interest or penalties related to unrecognized tax benefits.

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

Balance at October 1, 2009	$ 55,889
Increases/(decreases) as a result of tax positions taken during a prior period	(22,495)
Increases/(decreases) as a result of tax positions taken during the current period (including interest)	12,933
Balance at October 1, 2010	46,327
Increases/(decreases) as a result of tax positions taken during a prior period	1,846
Increases/(decreases) as a result of tax positions taken during the current period (including interest)	7,729
Balance at September 30, 2011	$ 55,902

The Company is subject to income tax examinations in the U.S. Federal jurisdiction, as well as in the United Kingdom, the Netherlands 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. The Company reduced its reserves during the year ended September 30, 2009 in accordance with ASC 740, *Income Taxes* for unrecognized tax benefits as a result of the settlement reached with the IRS.

10. Significant Customers

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

	September 30,		
	2011	2010	2009
Significant customers:			
Hollister	9%	10%	12%
Coloplast and Coloplast subsidiaries	10	14	10
Total	19%	24%	22%

11. Employee Benefit Plans

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, 2011, 2010 and 2009 was $149,348, $134,196 and $136,497, respectively. The Company also makes contributions to the Group Personal Pension Scheme for the benefit of the employees of its U.K. subsidiary.

12. Geographic Area Data

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

	September 30,		
	2011	2010	2009
Sales:			
United States	$18,400,000	$16,820,000	$14,447,000
United Kingdom	18,297,000	15,120,000	11,922,000
The Netherlands*	7,331,000	432,000	428,000
Europe & Middle East**	7,865,000	8,106,000	6,444,000
Rest of world	1,026,000	965,000	1,558,000
Total	$52,919,000	$41,443,000	$34,799,000

* The Company acquired Laprolan B.V. located in the Netherlands effective January 1, 2011.
** Europe sales exclude sales in the U.K. and the Netherlands.

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 intangible assets, of the Company are located in the United States, United Kingdom and the Netherlands as follows:

	September 30,	
	2011	2010
Long-lived assets:		
United States	$ 8,762,000	$ 8,668,000
United Kingdom	1,326,000	1,349,000
The Netherlands	1,965,000	—
Total	$12,053,000	$10,017,000

13. Line of Credit and Long-Term Debt

In June 2006, in conjunction with the asset purchase agreement with Coloplast, the Company entered into an unsecured loan note deed with Coloplast with an outstanding principal amount of $5,340,000. The promissory note was non-interest bearing, payable and due in five equal installments of $1,068,000 payable annually on June 2. The Company discounted the note at 6.90%. The final payment of $1,068,000 was paid in May 2011.

In December 2010, the Company entered into a credit facility with RBC Wealth Management. The credit facility consists of a revolving line of credit of up to $25,000,000 with interest accruing monthly at a variable rate of 1.375% at September 30, 2011. In conjunction with the closing of the Laprolan acquisition, on April 7, 2011, the Company drew down $15,057,775 from the line of credit. As of September 30, 2011, the Company had an outstanding balance under the revolving line of credit of $17,862,185.

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, 2011, the Company repurchased 156,834 shares. During fiscal 2011, the Company repurchased 284,585 shares of common stock pursuant to this program at an average price of $8.83 per share. Total cash consideration for the repurchased shares was approximately $2,500,000. As of September 30, 2011, there remained 1,429,847 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, 2011 and 2010 follows (in thousands, except per share amounts):

	Three Months Ended			
	December 31	March 31	June 30	September 30
Fiscal year 2011:				
Net sales	$10,946	$12,853	$14,281	$14,839
Gross profit	5,404	6,359	7,000	7,334
Income (loss) from operations	(465)	(1,309)	(491)	588
Net income (loss) before taxes	(460)	(1,393)	(535)	450
Net income (loss) per common share — basic	$ (.01)	$ (.10)	$ (.02)	$ .03
Net income (loss) per common share — diluted	$ (.01)	$ (.10)	$ (.02)	$ .03
Fiscal year 2010:				
Net sales	$10,232	$ 9,845	$10,244	$11,121
Gross profit	4,613	4,659	5,042	5,390
Income (loss) from operations	(298)	(202)	275	433
Net income (loss) before taxes	(310)	(226)	294	513
Net income (loss) per common share — basic	$ (.01)	$ (.03)	$ .01	$ .01
Net income (loss) per common share — diluted	$ (.01)	$ (.03)	$ .01	$ .01

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

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. 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. This evaluation did not include the internal controls related to the acquisition of Laprolan B.V. from Fornix BioSciences N.V. that occurred on April 7, 2011. Total assets and sales related to this acquisition represent 19.1% and 13.1%, respectively, of the related consolidated financial statement amounts as of and for the year ended September 30, 2011.

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, 2011, 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, 2011, (except for the information set forth under the subcaption "Compensation Committee Report on Executive Compensation") is incorporated herein by reference.

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

(a) Equity Compensation Plans. The following table provides information related to our equity compensation plans as of September 30, 2011:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders(1)	1,588,750	$9.39	527,000
Equity compensation plans not approved by security holders	—	—	—
Total	1,588,750	$9.39	527,000

(1) Includes shares issuable under our 2001 Stock Incentive Plan and 2010 Stock Incentive Plan.

(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, 2011, 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, 2011, is incorporated herein by reference.

ITEM 14. Principal Accounting Fees and Services

The information contained under the heading "Audit Committee Report and Payment of Fees to Auditors" in the Proxy Statement for Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the fiscal year ended September 30, 2011, 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, 2011 and 2010.

(ii) Consolidated Statements of Operations for the years ended September 30, 2011, 2010 and 2009.

(iii) Consolidated Statement of Shareholders' Equity and Comprehensive Income (Loss) for the years ended September 30, 2011, 2010 and 2009.

(iv) Consolidated Statements of Cash Flows for the years ended September 30, 2011, 2010 and 2009.

(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†	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).
10.2†	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).
10.3†	Change of Control Agreement dated December 4, 1998, between the Company and Philip J. Conway (Incorporated by reference to Exhibit 10.3 of Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 1998).
10.4†	Change of Control Agreement dated November 21, 2000, between the Company and Anthony J. Conway. (Incorporated by reference to Exhibit 10.6 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).

10.5†	Change of Control Agreement dated November 21, 2000, between the Company and Martyn R. Sholtis. (Incorporated by reference to Exhibit 10.9 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.6†	Change of Control Agreement dated November 21, 2000, between the Company and David A. Jonas. (Incorporated by reference to Exhibit 10.10 of the Registrant's Annual Report on Form 10-K for fiscal year ended September 30, 2000).
10.7†	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).
10.8†	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).
10.9†	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).
10.10†	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).
10.11†	The Company's Fiscal 2010 Management Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 19, 2009).
10.12†	The Company's Fiscal 2011 Management Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on November 23, 2010).
10.13	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).
10.14†	Rochester Medical Corporation 2010 Stock Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the registrant's Current Report on Form 8-K filed on February 1, 2010)
10.15†	Form of 2010 Stock Incentive Plan Incentive Stock Option Agreement for employees. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on February 1, 2010)
10.16†	Form of 2010 Stock Incentive Plan Non-Incentive Stock Option Agreement for employees. (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on February 1, 2010)
10.17†	Form of 2010 Stock Incentive Plan Non-Incentive Stock Option Agreement for directors (incorporated by reference to Exhibit 10.4 of the Registrant's Current Report on Form 8-K filed on February 1, 2010)
10.18†	Form of 2010 Stock Incentive Plan Restricted Stock Award Agreement. (Incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011)
10.19	Share Purchase Agreement, dated January 12, 2011, between Fornix BioSciences N.V. and the Company. (Incorporated by reference to Exhibit 2.1 of the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2011)
21*	Subsidiaries of the Company
23.1*	Consent of Grant Thornton 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).
101**	Financial statements from the Annual Report on Form 10-K of Rochester Medical Corporation for the year ended September 30, 2011, formatted in XBRL: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statement of Shareholders' Equity and Comprehensive Income (Loss), (iv) the Consolidated Statement of Cash Flows and (v) the Notes to the Consolidated Financial Statements.

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* Filed herewith.

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

** Furnished herewith.

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

Dated: December 9, 2011

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

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 9, 2011

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, 2011:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$54,048	$33,959	—	$43,412	$44,595
Year ended September 30, 2010:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$63,369	$32,543	—	$41,864	$54,048
Year ended September 30, 2009:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$65,202	$ —	—	$ 1,833	$63,369

(1) Uncollectible accounts written off net of recoveries

INDEX TO EXHIBITS

Exhibit	
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