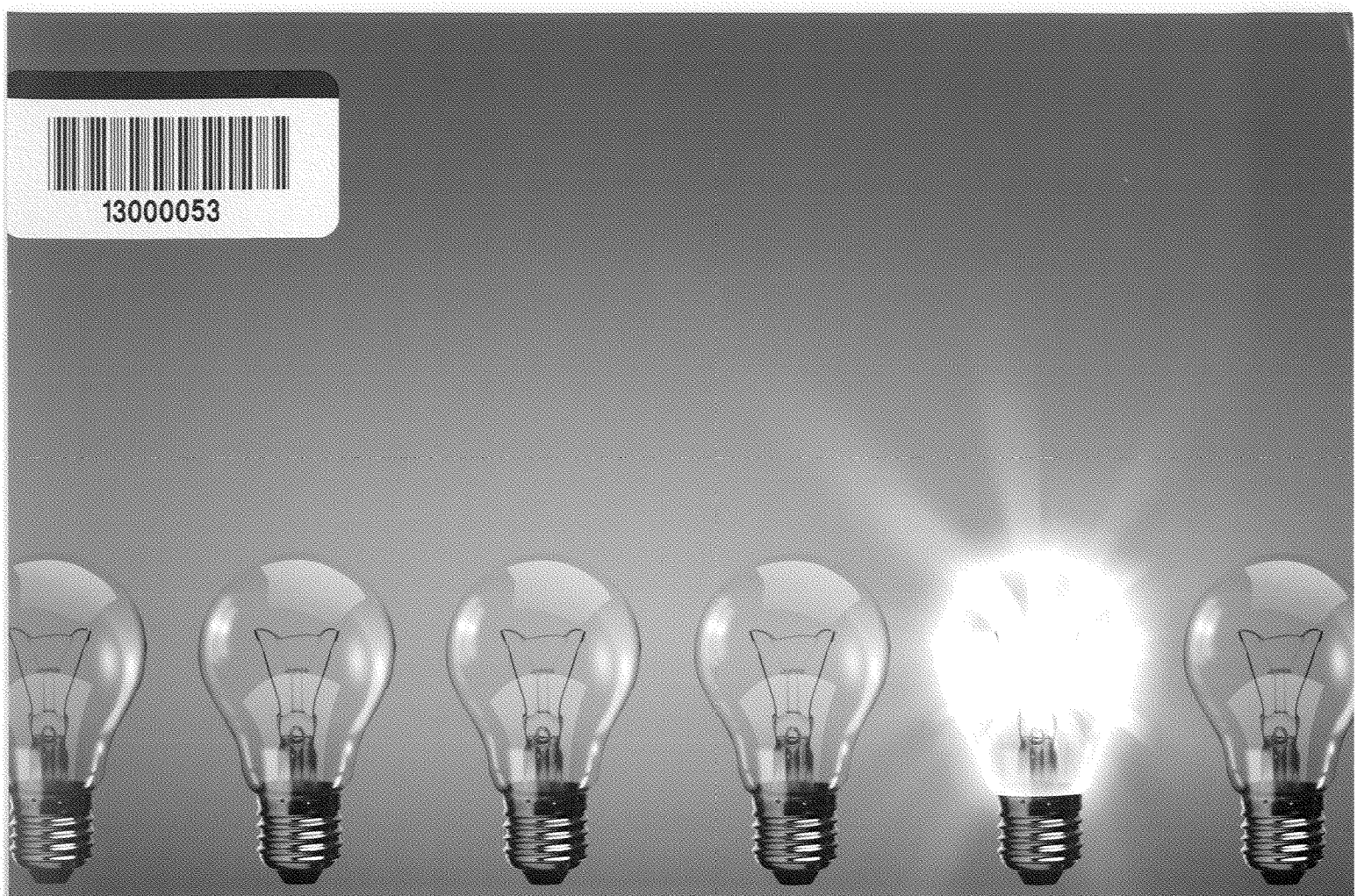


LEADING THE WAY WITH NEW IDEAS IN

INNOVATION

CONTINUALLY IMPROVING CONTINUALLY ADVANCING

WITH CONTINENCE CARE THAT IMPROVES LIVES

magic™

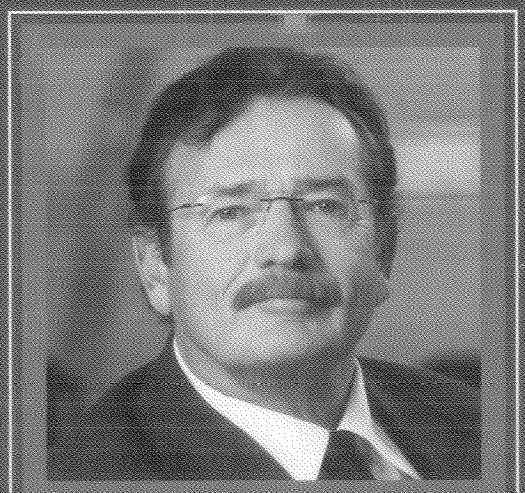
INTERMITTENT CATHETER

SPIRIT™

HYDROCOLLOID ADHESIVE BREATH

Rochester MEDICAL

FISCAL YEAR ENDING JULY 31 ANNUAL REPORT



ANTHONY J. CONWAY: *CEO & President*

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

2012

DEAR ROCM SHAREHOLDERS:

IT HAS BEEN AN **EXCITING & FULFILLING YEAR** FOR THE COMPANY.

Fiscal 2012 was a year of record sales and record income from operations, and I expect this trend to continue. Sales were especially strong in the United States and the United Kingdom, particularly in the Direct Home Care Market.

As we discussed with the investment community in November, sales of our Foley Catheters continued to lag our expectations despite significant resources directed to grow this product line. As such, the Company made a strategic decision to exit the Foley Catheter business since we could no longer justify the considerable expense and attention it required. We firmly believe the Company will be significantly stronger going forward as a result of this decision because it allows us to focus on our core product lines of Intermittent Catheters and Male External Catheters, both of which are profitable and growing steadily.

Fiscal 2012 marked another strong year for our Development and Sales and Marketing teams on the new product front. You will see featured in these pages several important new products introduced over the past year. We are very proud of the fact that Rochester Medical remains a leading innovator in our field. We are continuing to develop other exciting new technologies and expect they will lead to further growth in the future. To meet growing demand and enable production of these numerous advanced products, we recently broke ground on a new 54,000 square foot facility on our main campus in Stewartville, MN. We expect products to begin to flow out of this structure in late calendar 2013 or thereabouts.

I look forward to Rochester Medical posting continued growth and increasing profitability in the coming year. Thank you to all our employees and shareholders for helping us in our pursuit of success.

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, 2012

☐ **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 30, 2012 ($9.81) was $104,718,238.

Number of shares of common stock outstanding on December 7, 2012 was 12,142,050 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of Registrant's Proxy Statement for its 2013 Annual Meeting of Shareholders are incorporated by reference in Part III.

Table of Contents

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 patients who generally use such products at home. A small percentage of our urological products also are used in the acute care market, which generally includes hospitals and extended care treatment facilities. We also sell certain ostomy and wound and scar care products and other brands of urological products into the European marketplace.

Our urological products include a full line of silicone male external catheters, or MECs, for managing male urinary incontinence and a line of intermittent catheters for managing both male and female urinary retention, including our *Magic3*® advanced line of silicone intermittent catheters. Along with our silicone MECs, we also sell a line of latex MECs exclusively in the United Kingdom. Our products also include the *FemSoft*® *Insert*, a soft, liquid-filled, conformable urethral insert for managing stress urinary incontinence in adult females. Through our 2012 fiscal year, our urological products included a line of standard Foley catheters, our *Strata*® brand of advanced Foley catheters, and our *StrataNF*® *Catheter*, an antibacterial Foley catheter that reduces the incidence of hospital acquired urinary tract infection, or UTI. Our Foley catheters were sold primarily into the acute care market. In order to improve our profitability, we have decided to cease manufacturing and marketing our Foley catheters and focus on our core product lines of MECs and intermittent catheters.

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, or GPOs. 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 are self-care, disposable devices for managing male urinary incontinence. We manufacture and market seven models of silicone MECs: the *UltraFlex*®, *Pop-On*®, *Wide Band*®, *Natural*®, *Clear Advantage*®, *Transfix*® *and Spirit* ™ 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. In October 2012, we launched our *Spirit* Hydrocolloid Adhesive Sheath as our next generation of MECs that combines the moisture-wicking properties of hydrocolloid adhesive with the superior breathability of silicone.

All models of our MECs are produced in five sizes for better patient fit. Most of our MECs 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. In May 2012, we added the *Magic3* hydrophilic catheter with a Coude tip and insertion sleeve to the *Magic3* product line, which provides the added benefits of a touch-free gripping device combined with a specially designed curved tip configuration designed to aid insertion.

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

Through our fiscal year ended September 30, 2012, our urological products included a line of Foley catheters targeted to the acute care market under the *Rochester Medical* brand and under private label arrangements. In November 2012, we announced our decision to cease manufacturing and marketing Foley catheters. Costs and expenses associated with manufacturing and marketing Foley catheters are extensive, and this product line had not yet reached a point of positive earnings contribution. As such, we estimate our decision to exit this business will

significantly enhance our profitability. We will continue to own the intellectual property associated with our Foley catheters in anticipation of deriving additional value from those assets in the future.

Foley Catheters. We offered 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 were 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 allowed 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 offered 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.

Other Products

Through our 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 several members to our sales team. As of September 30, 2012, our U.S. direct sales force consisted of 34 members, which has been reduced to 21 members following our decision to exit the Foley catheter business. Internationally, we sell our *Rochester Medical* branded products in the United Kingdom through a direct sales force of 29 members, and in the Netherlands through a direct sales force of twelve members as of September 30, 2012, 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 20% of total sales in fiscal 2012. In fiscal 2011 and fiscal 2010, private label sales comprised 22% and 28% of total sales, respectively. Sales to Coloplast and to Hollister Incorporated ("Hollister") under private label arrangements each accounted for 9% of net sales for fiscal 2012.

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 $43 billion in contract purchases per year. Premier is owned by more than 200 leading not-for-profit hospitals and health care systems affiliated with some 2,500 hospitals and 80,000 other healthcare sites. The contract includes our 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. Novation provides contracting services to more than 65,000 members of VHA, Inc., the University HealthSystem Consortium, or UHC, and Provista (formerly HPPI), and manages more than $40 billion in contract purchases. We have also been awarded a urological products contract with Broadlane Inc. through October 2014. 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 that manages $48 billion in supply spend and serves more than 4,200 hospitals and 100,000 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 where we have a direct sales force) and other international markets. These arrangements are conducted under the *Rochester Medical* brand name and under brands controlled by the medical product companies. Our products are currently marketed in more than 75 countries. International sales (including the U.K. and the Netherlands) accounted for 63%, 65% and 59% of total sales in fiscal 2012, 2011 and 2010, 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 MECs. A second building houses our liquid encapsulation manufacturing operations, as well as our *FemSoft Insert* and intermittent catheter manufacturing lines. We have begun construction of a new 54,000 square foot intermittent catheter manufacturing facility that is expected to be operational in late calendar 2013.

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 each of our production lines. Our manufacturing facilities have been designed to accommodate the specialized requirements for the manufacture of medical devices, including the U.S. Food and Drug Administration's (FDA) requirements for Quality System Regulation, or QSR. An FDA audit of our facilities was successfully completed in 2012.

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.

Research and development expense for fiscal years 2012, 2011 and 2010 was $1,190,000, $1,009,000 and $1,235,000 which constituted 2%, 2% and 3% respectively, of net sales. Research and development expense includes research, product development and intellectual property. We expect that our research and development expense will be 2% of net sales in fiscal 2013.

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, Coloplast, Teleflex Incorporated and Wellspect HealthCare. 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 regulations administered by the FDA under the Federal Food, Drug and Cosmetic Act, including regulations concerning the prerequisites to commercial marketing, the conduct of clinical investigations, compliance with QSR and labeling. The FDA classifies medical devices and services into one of three classes based upon controls the FDA considers necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls such as labeling, adherence to good manufacturing practices and maintenance of product complaint records, but are usually exempt from premarket notification requirements. Class II devices are subject to the same general controls and also are subject to special controls such as performance standards and FDA guidelines, and may also require clinical testing prior to approval. Class III devices are subject to the highest level of controls because they are used in life-sustaining or life-supporting implantable devices. Class III devices require rigorous clinical testing prior to their approval and generally require a premarket approval (PMA) or supplement application prior to their sale.

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 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 2012, 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. For example, a change to reimbursement policies in 2009 increased the availability of reimbursement for intermittent catheters for patients from four catheters per month to 200 catheters per month.

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, 2012, we employed 344 full-time employees, of whom 159 were in manufacturing, 112 in sales and marketing, and the remainder in research and development and administration. As of such date, we also had 70 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	68	Chairman of the Board, Chief Executive Officer and President
Robert M. Anglin	45	Vice President, Quality and Regulatory
James M. Carper	61	Vice President, U.S. Sales and Marketing
Philip J. Conway	55	Vice President, Production Technologies
Sarah L. Grinde	39	Vice President, Development & Research
David A. Jonas	48	Director, Chief Financial Officer, Treasurer and Secretary
Martyn R. Sholtis	53	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.

Sarah L. Grinde joined us in November 2006 and serves as our Vice President of Development & Research. Ms. Grinde is responsible for project management, product development and business activities related to the strategic deployment and introduction of new technologies and products on a global basis. From 2006 to November 2011, Ms. Grinde served in a variety of marketing roles specifically focused on development and introduction of new products. In December 2011, Ms. Grinde was promoted to Project Development Manager responsible for project management as well as invention and development of new technologies, before assuming her current position in November 2012. Ms. Grinde holds a BS degree in Business Administration from Mayville State University.

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 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

Through our fiscal year ended September 30, 2012, our urological products included a line of Foley catheters targeted to the acute care market under the *Rochester Medical* brand and under private label arrangements. In November 2012, we announced our decision to cease manufacturing and marketing Foley catheters and focus on our core product lines of MECs and intermittent catheters. Costs and expenses associated with manufacturing and marketing Foley catheters are extensive, and this product line had not yet reached a point of positive earnings contribution. As such, we estimate our decision to exit this business will significantly enhance our profitability. We will continue to fulfill orders for an interim period following our announcement, during which time we expect to deplete the majority of our Foley inventory, and will continue to own the intellectual property associated with our Foley catheters in anticipation of deriving additional value from those assets in the future.

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 several members to our sales team. As of September 30, 2012, our U.S. direct sales force consisted of 34 members, which has been reduced to 21 members following our decision to exit the Foley catheter business. Internationally, we sell our *Rochester Medical* branded products in the United Kingdom through a direct sales force of 29 members, and in the Netherlands through a direct sales force of twelve members as of September 30, 2012, respectively.

Additionally, we have began construction of a new 54,000 square foot intermittent catheter manufacturing facility, located in our Stewartville, MN campus, that is expected to be operational in late calendar 2013. The total cost is anticipated to be approximately $12,000,000.

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 income for the 2012 fiscal year was $2,050,000, while we experienced net losses of $(1,315,000) for fiscal 2011 and $(254,000) for fiscal 2010. The objective of our three year strategic plan that we adopted at the beginning of fiscal 2011 was to double our annual overall sales during the three fiscal years of the plan, while also producing a significant increase in net income in the third year. As part of that plan, we increased the level of investment in our sales and marketing programs to support our direct sales growth in the U.S. and Europe through the addition of several members to our sale team, with the increased investment expected to be funded primarily through cash generated from operations. We recently updated our three-year strategic plan, primarily as a result of the discontinuation of our Foley catheter line and, to a lesser extent, a more conservative assumption regarding international sales given the broader economic challenges in Europe. 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. While we still expect significant growth in sales as a result of our three-year strategic plan, 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 and again in 2012, we cannot be certain that we will be able to sustain or increase profitability on a quarterly or annual basis.

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 2012 represented approximately 31% 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 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 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 increased 6% in fiscal 2012 compared to fiscal 2011, but represented 20% of total net sales in fiscal 2012 compared to 22% in fiscal 2011. 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 have increased the level of investment in our sales and marketing programs to support our direct sales growth in the U.S. and Europe through the addition of several 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 of 2010 were enacted into law in March 2010. Certain provisions of the law 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 on us or the U.S. economy from the legislation. The law 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 2012, this would have equated to an excise tax of approximately $234,000. The law 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 that began in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending beginning in 2014. 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 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, or expose us to enforcement actions and penalties

We operate in several parts of the world, and our operations are affected by various state, federal and international healthcare, antitrust, anti-corruption and employment laws, including, for example, various FDA and international regulations, the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act and the UK Bribery Act. The failure to comply with these laws and regulatory standards or the discovery of previously unknown problems with a product or our manufacturing processes could result in (i) warning letters, fines, delays or suspensions of regulatory clearances, detainment, seizures or recalls of products (with the attendant expenses), the banning of a particular device, an order to replace or refund the cost of any device previously manufactured or distributed, operating restrictions and/or civil or criminal prosecution, and/or penalties, as well as decreased sales as a result of negative publicity and product liability claims; and (ii) could have a material adverse effect on our business, results of operations, financial condition and/or liquidity.

Our products, product development activities, marketing 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 into the market 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 63% of our net sales in fiscal 2012. 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 75 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. Our sales and profitability from our international operations and our ability to implement our overall business strategy are subject to risk and uncertainties that can vary country by country. 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.

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 net sales and net income. Fluctuations between the currencies in which we do business have caused and will continue to cause foreign currency translation 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 collect or timely collect outstanding receivables.

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.

In addition, the U.S. Foreign Corrupt Practices Act (FCPA) and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. Because of the predominance of government-sponsored health care systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. Despite meaningful measures that we undertake to facilitate lawful conduct, which include training and internal control policies, these measures may not always prevent reckless or criminal acts by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction and result in a material adverse effect on our business, financial condition and results of operations. We also could suffer severe penalties, including criminal and civil penalties, disgorgement, further changes or enhancements to our procedures, policies and controls, personnel changes and other remedial actions.

Furthermore, we are subject to the export controls and economic embargo rules and regulations of the United States, including the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons. While we train our employees to comply with these regulations, we cannot assure that a violation will not occur, whether knowingly or inadvertently. Failure to comply with these rules and regulations may result in substantial penalties, including fines and enforcement actions and civil and criminal sanctions, the disgorgement of profits and the imposition of a court-appointed monitor, as well as the denial of export privileges and debarment from participation in U.S. government contracts.

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.

Failure to integrate acquired businesses into our operations successfully could adversely affect our business.

As part of our strategy to grow our business, we have made acquisitions in recent years and may make additional acquisitions in the future. In April 2011, we completed the acquisition of Laprolan B.V., which distributes into the European market 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 *RochesterMedical* branded products. However, we may not be able to identify other suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. Our integration of the operations of acquired businesses requires significant efforts, including the coordination of information technologies, sales and marketing, general and administrative operations, and finance. These efforts result in additional expenses and involve significant amounts of management's time that cannot then be dedicated to other projects. Our failure to manage successfully and coordinate the growth of the combined company could also have an adverse impact on our business. In addition, we cannot be certain that the businesses we acquire will become profitable or remain so. If our acquisitions are not successful, we may record unexpected impairment charges. Factors that will affect the success of our acquisitions include:

- the presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies;

- adverse developments arising out of investigations by governmental entities of the business practices of acquired companies;
- any decrease in customer loyalty and product orders caused by dissatisfaction with the combined companies' product lines and sales and marketing practices, including price increases;
- our ability to retain key employees; and
- the ability of the combined company to achieve synergies among its constituent companies, such as increasing net sales of the combined company's products, achieving cost savings and effectively combining technologies to develop new products.

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.

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. As a result, a reduction or interruption in manufacturing could have a material adverse effect on our business and/or results of operations.

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 $6 million per product liability claim, with an annual aggregate limit of $11 million under the policies. 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.

Current economic instability 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, and conditions could worsen. 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 the economy in the United States has begun to recover, the recovery has been below historic averages and the strength and timing of an economic recovery remains uncertain, which could continue to adversely affect our operations and results in fiscal 2013. If the U.S. government is unable to reach agreement on legislation addressing the United States' current debt level and budget deficit, many economists have predicted another economic recession. Proposed cuts in federal spending over the next decade could result in cuts to, and restructuring of, entitlement programs such as Medicare and aid to states for Medicaid programs. Our hospital customers rely heavily on Medicare and Medicaid programs to fund their operations. Any cuts to these programs could negatively affect the business of our customers and our business.The economies of Europe and other regions may also remain distressed well into 2013 or longer, which could continue to adversely affect our operations and results in fiscal 2013. 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 volume of 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, collaborative 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 have begun construction of a new 54,000 square foot intermittent catheter manufacturing facility that is expected to be operational in late calendar 2013. We also own a 13,000 square foot office building/warehouse in Lancing, England and an 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, and our new manufacturing facility will be adequate to meet our needs for the foreseeable future. Our current manufacturing facilities in Stewartville, Minnesota could also 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.

ITEM 4. Mine Safety Disclosures

Not applicable.

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 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
Fiscal 2012		
First Quarter	$ 8.30	$ 6.68
Second Quarter	10.10	7.45
Third Quarter	10.90	9.46
Fourth Quarter	12.45	9.93

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 2012, we repurchased a total of 150,900 shares of common stock pursuant to this program. As of September 30, 2012, there remained 1,278,947 shares that may be purchased under the program. During the three months ended September 30, 2012, no shares were repurchased.

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

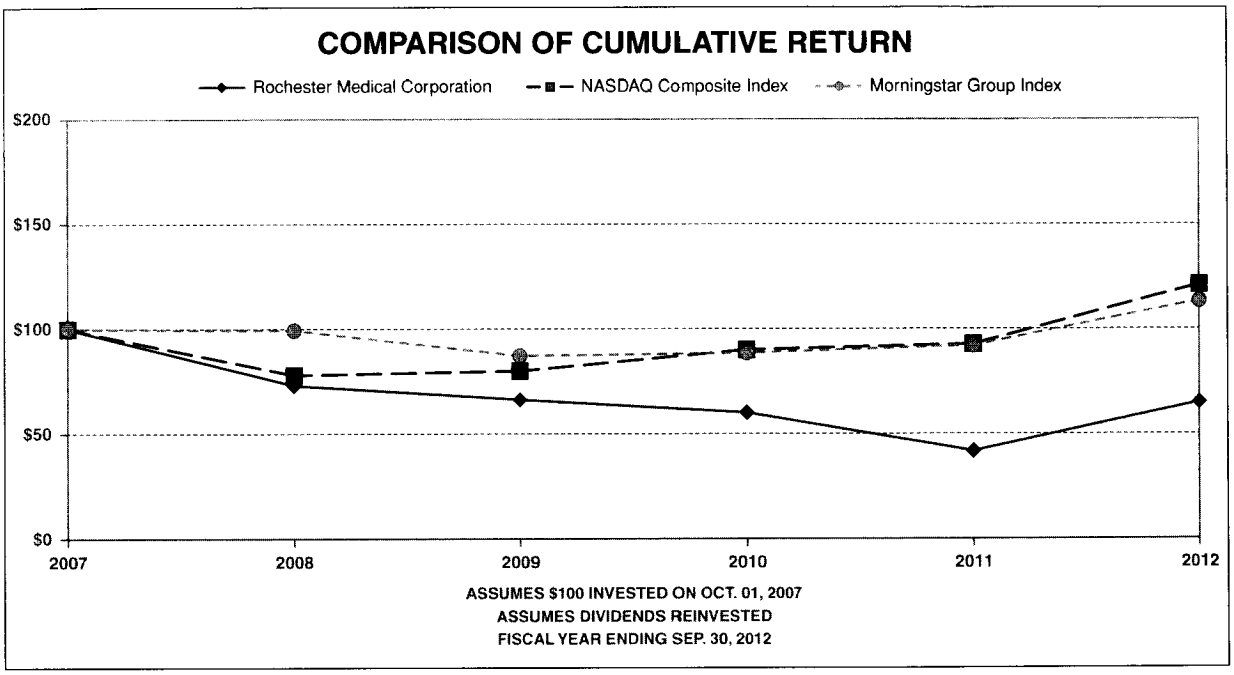
As of December 7, 2012, we had 122 shareholders of record. Such number of record holders does not reflect shareholders who beneficially own common stock in nominee or street name.

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, 2012. The comparison assumes $100 was invested on October 1, 2007 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 Ended September 30,					
	2007	2008	2009	2010	2011	2012
Rochester Medical Corporation	$100	$73.06	$66.34	$60.11	$41.82	$ 65.07
Morningstar Group Medical Instruments and Supplies Index	100	99.30	87.20	88.59	92.12	113.35
Nasdaq Composite Index	100	78.01	79.98	90.07	92.73	121.04

ITEM 6. Selected Financial Data

The following selected financial data of Rochester Medical Corporation as of September 30, 2012 and 2011 and for the fiscal years ended September 30, 2012, 2011 and 2010, 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, 2010, 2009 and 2008 and for the fiscal years ended September 30, 2009 and 2008 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,				
	2012	2011	2010	2009	2008
	(In thousands, except for per share data)				
Net sales	$61,683	$53,373	$41,548	$34,904	$35,369
Cost of sales	30,866	26,724	21,509	17,861	18,305
Gross profit	30,817	26,649	20,039	17,043	17,064
Operating expenses:					
Marketing and selling	18,244	18,814	12,204	10,544	9,855
Research and development	1,190	1,009	1,235	1,241	1,044
General and administrative	8,170	8,503	6,391	6,007	6,658
Total operating expenses	27,604	28,326	19,830	17,792	17,557
Income (loss) from operations	3,213	(1,677)	209	(749)	(493)
Other income	—	—	—	1,200	1,240
Interest income (expense), net	(131)	(261)	61	24	(566)
Net income (loss) before income tax	3,082	(1,938)	270	475	181
Income tax benefit (expense)	(1,032)	623	(524)	(366)	578
Net income (loss)	$ 2,050	$ (1,315)	$ (254)	$ 109	$ 759
Net income (loss) per common share — basic	$ .17	$ (.11)	$ (.02)	$ .01	$ .06
Net income (loss) per common share — diluted	$ .17	$ (.11)	$ (.02)	$ .01	$ .06
Weighted average number of common shares outstanding — basic	12,032	12,218	12,182	12,045	11,816
Weighted average number of common shares outstanding — diluted	12,340	12,218	12,182	12,640	12,577

	As of September 30,				
	2012	2011	2010	2009	2008
	(in thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$20,701	$34,905	$35,513	$36,262	$37,002
Working capital	38,109	34,211	47,605	48,552	48,772
Total assets	75,931	90,470	75,666	75,965	76,983
Long-term debt and capital lease obligations	1,137	896	46	1,076	4,046
Retained earnings	15,314	13,263	14,579	14,833	14,724
Total shareholders' equity	68,296	65,977	68,893	68,820	67,699

No dividends were declared or paid in any year from 2008 to 2012.

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 patients who generally use such products at home. A small percentage of our urological products also are used in the acute care market, which generally includes hospitals and extended care treatment facilities. Through our recently acquired subsidiary, Laprolan B.V., we also sell certain ostomy and wound and scar care products and other brands of urological products into the European marketplace. 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 63% and 65% of total sales in the fiscal years ended September 30, 2012 and 2011, respectively.

The urological products we manufacture include our silicone male external catheters (MECs), our standard and advanced lines of silicone and anti-infection intermittent catheters and our *FemSoft Insert*. Through our fiscal year ended September 30, 2012, we also manufactured standard and advanced lines of silicone and anti-infection Foley catheters for the acute care market. In November 2012, we announced our decision to cease manufacturing and marketing Foley catheters, and will focus on our core product lines of MECs and intermittent catheters. Net sales of Foley catheters were approximately $4.0 million for fiscal 2012, representing approximately 6% of our total net sales. Costs and expenses associated with manufacturing and marketing Foley catheters are extensive, and this product line had not yet reached a point of positive earnings contribution. As such, we estimate our decision to exit this business will significantly enhance our profitability. We will continue to fulfill orders for Foley catheters for up to 90 days from announcement, during which time we expect to deplete the majority of our remaining Foley inventory. We will continue to own the intellectual property associated with our Foley catheters in anticipation of deriving additional value from those assets in the future.

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 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 several members to our sales team. As of September 30, 2012, our U.S. direct sales force consisted of 34 members, which has been reduced to 21 members following our decision to exit the Foley catheter business. Internationally, we sell our *Rochester Medical* branded products in the United Kingdom through a direct sales force of 29 members, and in the Netherlands through a direct sales force of twelve members as of September 30, 2012, 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 2012, the *Script-Easy* program contributed $12.8 million of net sales compared to $10.4 million in fiscal 2011, 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. 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 B. 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 B. 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 B. in our financial statements beginning with the second quarter of our fiscal 2011.

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 20% of total sales in fiscal 2012, compared to 22% of total sales in fiscal 2011. 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, 2012 were $61.7 million, an increase of $8.3 million, or 16%, from $53.4 million in the prior fiscal year. The increase in net sales resulted from an 18% increase in direct sales for the fiscal year, while private label sales increased 6% 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, as well as an increase in sales to the acute care market in the U.S., offset by a decrease in acute care sales internationally. Home care direct sales accounted for 89% of total direct sales for our fiscal year ended September 30, 2012.

Our five largest customers in fiscal 2012 represented approximately 31% 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.

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.

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.

As of September 30, 2012, we had $13.9 million in cash and cash equivalents, and $6.8 million invested in marketable securities. The marketable securities primarily consist of $6.3 million invested in U.S. treasury bills and $.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.

Our net income for fiscal 2012 was $2,050,000, or $.17 per diluted share compared to a net loss of $(1,315,000), or $(.11) per diluted share, in fiscal 2011. The increase in net income for fiscal 2012 compared to fiscal 2011 primarily resulted from increased sales as well as reduced operating expenses incurred in 2012.

The objective of our three year strategic plan that we adopted at the beginning of fiscal 2011 was to double our annual overall sales during the three fiscal years of the plan, while also producing a significant increase in net income in the third fiscal year. As part of that plan, we increased the level of investment in our sales and marketing programs to support our direct sales growth in the U.S. and Europe through the addition of several members to our sales team, with the increased investment expected to be funded primarily through cash generated from operations. We recently updated our three-year strategic plan, primarily as a result of the discontinuation of our Foley catheter line and, to a lesser extent, a more conservative assumption regarding international sales given the broader economic challenges in Europe, although we still expect significant growth in sales and improved net income as a result of our strategic plan and the higher level of profitability we expect to achieve following our exit of the Foley catheter business. 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. 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, but we expect quarterly fluctuations in sales to diminish as private label sales represent a smaller percentage of total sales. 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, 2012, this reserve was $148,000 compared to $166,000 at September 30, 2011. 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, 2012, this allowance was $86,000

compared to $45,000 at September 30, 2011. 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 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, Netherlands, 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, 2012, we recorded a valuation allowance of $216,000 of which $42,000 is related to Minnesota R&D credit and $174,000 pertains to U.S. federal capital loss carryovers as we believe it is more likely than not that these deferred tax assets 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, 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. We test annually for impairment of the asset, currently on June 1st of each fiscal year for the goodwill

associated with our 2006 U.K. acquisition and for the goodwill related to our 2011 Netherlands acquisition. 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 approximately $9.1 million as of September 30, 2012 and 2011.

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 $9.4 million and $10.3 million as of September 30, 2012 and 2011, 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. Total stock-based compensation expense recognized during the fiscal year ended September 30, 2012 was approximately $600,000 after-tax ($1.0 million pre-tax). See Note 7 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 use the intrinsic value method to estimate the value of restricted stock awards.

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 income and diluted net income per share of a future period. There were no modifications to any of our plans in 2012.

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,		
	2012	2011	2010
Net sales	100.0%	100.0%	100.0%
Cost of sales	50.0	50.1	51.8
Gross margin	50.0	49.9	48.2
Operating expenses:			
Marketing and selling	29.5	35.2	29.3
Research and development	1.9	1.9	3.0
General and administrative	13.2	15.9	15.4
Total operating expenses	44.6	53.0	47.7
Income (loss) from operations	5.4	(3.1)	0.5
Other income	—	—	—
Interest income (expense), net	(0.4)	(0.5)	0.2
Net income (loss) before income taxes	5.0%	(3.6)%	0.7%

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 Year to Date ended Sept 30, 2012							
	2012				2011			
	US	Europe & Middle East	Rest of World	Total	US	Europe & Middle East	Rest of World	Total
Net Sales								
Acute Care — Direct	$ 3,229	$ 1,758	$ 477	$ 5,464	$ 2,486	$ 1,923	$ 457	$ 4,866
Home Care — Direct	$10,667	$32,638	$ 547	$43,852	$ 8,043	$28,239	$ 558	$36,840
Direct Total	$13,896	$34,396	$1,024	$49,315	$10,529	$30,162	$1,015	$41,706
Private Label	$ 9,027	$ 3,317	$ 24	$12,368	$ 8,188	$ 3,455	$ 24	$11,667
Total Revenues	$22,922	$37,713	$1,048	$61,683	$18,717	$33,617	$1,039	$53,373
Direct Product Mix								
Acute Care — Direct	23%	5%	47%	11%	24%	6%	45%	12%
Home Care — Direct	77%	95%	53%	89%	76%	94%	55%	88%
Direct Total	100%	100%	100%	100%	100%	100%	100%	100%
Direct Geographic Mix								
Acute Care — Direct	6%	4%	1%	11%	6%	5%	1%	12%
Home Care — Direct	22%	66%	1%	89%	19%	68%	1%	88%
Direct Total	28%	70%	2%	100%	25%	73%	2%	100%
YOY Sales Growth								
Direct	32%	14%	1%	18%				
Private Label	10%	(4)%	2%	6%				
Total Revenues	22%	12%	1%	16%				

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, 2012 Compared to Fiscal Year Ended September 30, 2011

Net Sales. Net sales increased 16% to $61.7 million in fiscal 2012 from $53.4 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., an increase in private label sales in the U.S., offset by a slight decrease in EME 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 home care sales in the rest of the world ("ROW") and acute care sales in the U.S., offset by a slight decrease in acute care sales in the ROW and EME. U.S. direct sales increased by 32% over last fiscal year. Our EME direct sales increased 14% compared to last year led by a strong increase in the U.K. and twelve months of revenue from Laprolan versus nine months of revenue the prior year. 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 catheters, which we believe will continue to drive growth in branded sales. Total net sales for the fiscal year were negatively affected by $975,000 as a result of the stronger U.S. dollar versus the pound sterling and the euro, thereby affecting sales given the significant volume of our *Rochester Medical* branded product sales in the United Kingdom and the Netherlands. Direct sales in the ROW were flat compared to the same period last year. Private label sales were up

$701,000 from last year. Private label sales accounted for approximately 20% of total sales in fiscal 2012 compared to 22% 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 50% in fiscal 2012, unchanged from fiscal 2011. Increased sales and higher mix of lower margin products, particularly new advanced intermittent catheters and Foley catheters, offset manufacturing efficiencies and increased sales of higher margin products, particularly MECs. Management expects the sale of our new advanced intermittent catheters 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. Our exit from the Foley catheter business should also have a positive impact on gross margin.

Marketing and Selling. Marketing and selling expense primarily includes costs associated with base salary paid to sales and marketing personnel, sales commissions, and travel and advertising expense. Marketing and selling expense decreased 3% in fiscal 2012 as compared to fiscal 2011, with marketing and selling expense of approximately $18.2 million in fiscal 2012 and $18.8 million in fiscal 2011. The decrease in marketing and selling expense is primarily due to $83,000 of decreased travel expenses, $498,000 of decreased advertising and project costs primarily for acute care partially offset by increases for home care and new intermittent catheter product launches, $34,000 of decreased freight costs and a $180,000 decrease in consulting fees, partially offset by $225,000 of increased compensation expenses for our home care sales and marketing team. Marketing and selling expense as a percentage of net sales for fiscal 2012 was 30% compared to 35% for fiscal 2011.

Research and Development. Research and development expense primarily includes internal labor costs, materials used to develop new products, as well as expense associated with third-party vendors performing validation and investigative research regarding our products and development activities. Research and development expense increased to $1.2 million in fiscal 2012 compared to $1.0 million in fiscal year 2011. The increase was primarily related to the addition of our Vice President, Development & Research. Research and development expense as a percentage of net sales for fiscal 2012 and fiscal 2011 was 2% and 2%, 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 decreased to $8.2 million in 2012 from $8.5 million in fiscal 2011. The changes in general and administrative expense primarily related to a decrease of the one-time costs associated with the acquisition of Laprolan incurred in fiscal 2011, decreases of $34,000 in compensation expenses and $58,000 in travel, and increases of $103,000 in depreciation. General and administrative expense as a percentage of net sales for fiscal 2012 and fiscal 2011 was 13% and 16%, respectively.

Interest Income. Interest income decreased 69% to $43,000 in fiscal 2012 from $140,000 in the prior fiscal year. The decrease reflects overall lower interest rates on investments and lower cash available for investment following the payoff of our line of credit balance.

Interest Expense. Interest expense decreased 68% to $90,000 in fiscal 2012 from $277,000 in fiscal 2011. The decrease in interest expense reflects lower amounts of debt as a result of paying off the outstanding balance on our line of credit originally incurred to finance our acquisition of Laprolan.

Income Taxes. During the current fiscal year we utilized federal net operating losses (NOLs) of approximately $456,000 and have approximately $1.6 million remaining. We have U.K. NOL carry-forwards as of September 30, 2012 of approximately 51,000 pounds sterling (approximately $82,000). For fiscal 2012, we have a valuation allowance of $216,000 related to Minnesota R&D credit and U.S. federal capital loss carryovers as we believe it is more likely than not that these deferred tax assets 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 2012, we had an effective tax rate of approximately 34% resulting primarily from foreign operations, incentive stock options and other permanent differences. In future periods of taxable earnings, we expect an effective tax rate in the range of 30-34%.

Net Income (Loss). For fiscal 2012, we reported a net income of $2,050,000 compared to a net loss of $(1,315,000) in fiscal 2011. The increase in net income was primarily driven by increased sales resulting from our strategic investment in net sales and marketing programs and our focus on direct sales in home care markets as we executed on our three year strategic business plan.

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

Net Sales. Net sales increased 28% to $53.4 million in fiscal 2011 from $41.5 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. 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.

Gross Margin. Our gross margin as a percentage of net sales was 50% 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.

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 54% in fiscal 2011 as compared to fiscal 2010, with marketing and selling expense of approximately $18.8 million in fiscal 2011 and $12.2 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, $327,000 in freight and $58,000 increase in consulting fees. Marketing and selling expense as a percentage of net sales for fiscal 2011 was 35% 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 $1.0 million in fiscal 2011 compared to $1.2 million 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 $8.5 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 16% 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 fiscal 2011 we generated U.S. federal net operating losses (NOLs) of approximately $3.8 million. We had 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 did not record 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.

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.

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 $20.7 million at September 30, 2012, compared with $34.9 million at September 30, 2011. The decrease in cash primarily resulted from cash used for capital expenditures, stock repurchases and debt repayments, partially offset by cash provided by operations and from stock option exercises. As of September 30, 2012, we had $6.8 million invested in marketable securities. The marketable securities primarily consist of $6.3 million invested in U.S. treasury bills and $.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 generated a net $5.9 million of cash from operating activities during the year compared with $2.6 million for the same period last year, with the primary difference being positive net income and decreased levels of inventory offset by increased accounts receivable. Cash flow provided by operating activities in 2012 was comprised of net income of $2.0 million decreased by an increase in net working capital components of $.2 million and increased by net non-cash charges of $4.0 million, including depreciation and amortization of $2.7 million and stock-based compensation of $1.0 million. Significant working capital changes are as follows:

- a $2,260,000 increase in accounts receivable reflecting timing of cash collections over prior year and sales growth,
- a $1,426,000 decrease in inventory levels,
- a $650,000 decrease in deferred income taxes,
- a $52,000 increase in prepaid expenses and other current assets,
- a $278,000 increase in accounts payable reflecting timing of payments, and
- a $241,000 increase in income taxes payable.

During fiscal 2012, our working capital position, excluding cash and marketable securities, increased by $18.3 million as a result of the pay off of short term borrowings used to fund the acquisition of Laprolan. Accounts receivable balances increased $2.2 million during the fiscal year primarily due to growth in sales in the fourth quarter. Inventories as of September 30, 2012 decreased $1.4 million over fiscal 2011. Changes in other asset and liability balances related to timing differences.

Investing activities, primarily the sale of marketable securities offset by purchases of property, plant and equipment, provided net cash of $17.9 million in fiscal 2012.

Financing activities, primarily payments on short term debt and share repurchases, used net cash of $18.7 million in fiscal 2012.

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. In January 2012, we used a portion of our cash and cash equivalents and marketable securities and paid off our entire outstanding balance on our line of credit. The borrowings under this credit facility are limited to the value of eligible assets held with RBC Wealth Management. The credit facility now consists of a revolving line of credit of up to $5,000,000 with interest accruing monthly at a variable rate of 1.375% as of September 30, 2012. As of September 30, 2012, we had no outstanding balance under the revolving line of credit.

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, 2012:

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Contractual Obligations					
Unrecognized tax benefits under FIN 48(1)	$ 32,621	$ —	$ 32,621	$—	$—
Operating leases	1,458,190	654,504	803,686	—	—
Purchase obligations (general operating)	3,075,921	3,075,921	—	—	—
Total Contractual Obligations	$4,566,732	$3,730,425	$836,307	$—	$—

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

Off-Balance Sheet Arrangements

As of September 30, 2012, we did not have any significant off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, "*Presentation of Comprehensive Income*" which requires comprehensive income to be reported in either a single statement or in two consecutive statements reporting net income and other comprehensive income. The amendment does not change what items are reported in other comprehensive income. Additionally, in December 2011, the FASB issued ASU No. 2011-12, "*Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*" which indefinitely defers the requirement in ASU No. 2011-05 to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement in which net income is presented and the statement in which other comprehensive income is presented. During the deferral period, the existing requirements in U.S. GAAP for the presentation of reclassification adjustments must continue to be followed. These standards will be effective for our fiscal quarter beginning October 1, 2012 with retrospective application required. As these standards impact presentation requirements only, the adoption of this guidance will not have an impact on our results of operations or financial position.

In September 2011, the FASB issued ASU No. 2011-08, *"Testing Goodwill for Impairment"* that is intended to simplify how entities test goodwill for impairment. This ASU permits an entity to first assess qualitative factors to determine whether it is "more likely than not" that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC Topic 350, "*Intangibles — Goodwill and Other.*" This update is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 (our fiscal 2013). This standards update is not expected to have a material impact on our 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 and increasing our direct sales;
- 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 uncertainty of securing 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;
- current economic instability in the U.S. and international economies;
- 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.

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, 2012 we had no outstanding balance 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, 2012, 2011 and 2010

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
Rochester Medical Corporation

We have audited the accompanying consolidated balance sheets of Rochester Medical Corporation (a Minnesota corporation) and subsidiaries (collectively, the "Company") as of September 30, 2012 and 2011, 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, 2012. Our audits of the basic consolidated 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 provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Rochester Medical Corporation and subsidiaries as of September 30, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 2012, 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 consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of September 30, 2012, 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 19, 2012 expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
December 19, 2012

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, 2012, 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.

A material weakness is a deficiency, or combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. The Company had misinterpreted the accounting standards related to the classification of shipping and handling fees and related costs and the misinterpretation was not identified in management's review of the financial statement reporting disclosures.

In our opinion, because of the effect of the material weakness described above on the achievement of the objectives of the control criteria, Rochester Medical Corporation has not maintained effective internal control over financial reporting as of September 30, 2012, based on criteria established in *Internal Control — Integrated Framework* issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Rochester Medical Corporation as of September 30, 2012 and 2011, 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, 2012. The material weakness identified above was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2012 financial statements, and this report does not affect our report dated December 19, 2012, which expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
December 19, 2012

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED BALANCE SHEETS

	September 30, 2012	September 30, 2011
Assets:		
Current assets:		
Cash and cash equivalents	$ 13,921,363	$ 8,722,935
Marketable securities	6,779,695	26,182,308
Accounts receivable, less allowance for doubtful accounts ($86,268 – 2012; $44,595 – 2011)	11,008,429	8,644,332
Inventories	9,883,651	11,278,694
Prepaid expenses and other current assets	1,726,908	1,361,259
Deferred income tax asset	1,287,177	1,618,495
Total current assets	44,607,223	57,808,023
Property, plant and equipment:		
Land	1,111,314	1,115,883
Buildings	9,539,813	9,455,840
Equipment and fixtures	20,550,952	19,531,006
	31,202,079	30,102,729
Less accumulated depreciation	(19,340,007)	(18,050,044)
Total property, plant and equipment	11,862,072	12,052,685
Deferred income tax asset	1,030,994	1,242,010
Goodwill	9,053,091	9,094,725
Intangible assets, less accumulated amortization ($4,628,474 – 2012; $3,682,633 – 2011)	9,191,727	10,061,655
Patents, less accumulated amortization ($1,385,266 – 2012; $1,328,486 – 2011)	185,627	211,016
Total assets	$ 75,930,734	$ 90,470,114
Liabilities and Shareholders' Equity:		
Current liabilities:		
Accounts payable	$ 3,070,329	$ 2,773,398
Accrued compensation	1,970,468	1,460,726
Accrued expenses	1,456,929	1,500,544
Current maturities of debt	—	17,862,185
Total current liabilities	6,497,726	23,596,853
Long-term liabilities	1,137,212	896,414
Shareholders' equity:		
Common stock, no par value:		
Authorized shares — 40,000,000		
Issued and outstanding shares: (12,120,050 – 2012; 12,141,817 – 2011)	56,904,308	56,829,350
Retained earnings	15,313,858	13,263,374
Accumulated other comprehensive loss	(3,922,370)	(4,115,877)
Total shareholders' equity	68,295,796	65,976,847
Total liabilities and shareholders' equity	$ 75,930,734	$ 90,470,114

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

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

	Fiscal Years Ended September 30,		
	2012	2011	2010
Net sales	$61,683,201	$53,372,698	$41,547,788
Cost of sales	30,865,556	26,723,946	21,509,126
Gross profit	30,817,645	26,648,752	20,038,662
Operating expenses:			
Marketing and selling	18,244,034	18,814,445	12,203,733
Research and development	1,190,095	1,008,767	1,235,367
General and administrative	8,170,468	8,502,956	6,391,003
Total operating expenses	27,604,597	28,326,168	19,830,103
Income (loss) from operations	3,213,048	(1,677,416)	208,559
Other income (expense):			
Interest income	43,243	139,859	239,171
Other expense	(84,458)	(123,901)	—
Interest expense	(89,545)	(277,008)	(177,401)
Total other income (loss)	(130,760)	(261,050)	61,770
Income (loss) before income taxes	3,082,288	(1,938,466)	270,329
Income tax benefit (expense)	(1,031,804)	623,162	(523,864)
Net income (loss)	$ 2,050,484	$ (1,315,304)	$ (253,535)
Net income (loss) per common share — basic	$ .17	$ (.11)	$ (.02)
Net income (loss) per common share — diluted	$ .17	$ (.11)	$ (.02)
Weighted average number of common shares outstanding — basic	12,032,113	12,217,900	12,181,549
Weighted average number of common shares outstanding — diluted	12,339,500	12,217,900	12,181,549

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, 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)
Unrealized gain on available-for-sale securities, net of tax	—	—	—	84,871	84,871
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)
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(28,785)	(28,785)
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)
Restricted shares issued	40,000	—	—	—	—
Stock option exercises	313,950	646,917	—	—	646,917
Balance at September 30, 2011	12,141,817	56,829,350	13,263,374	(4,115,877)	65,976,847
Net income for the year	—	—	2,050,484	—	2,050,484
Foreign currency translation adjustment	—	—	—	(13,198)	(13,198)
Unrealized gain on available-for-sale securities, net of tax	—	—	—	206,705	206,705
Subtotal-comprehensive income					2,243,991
Stock based compensation	—	983,286	—	—	983,286
Restricted shares issued	61,883	—	—	—	—
Restricted shares canceled	(2,000)	—	—	—	—
Common stock repurchased	(150,900)	(1,088,619)	—	—	(1,088,619)
Stock option exercises	69,250	180,291	—	—	180,291
Balance at September 30, 2012	12,120,050	$56,904,308	$15,313,858	$(3,922,370)	$68,295,796

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

ROCHESTER MEDICAL CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Fiscal Years Ended September 30,		
	2012	2011	2010
Operating Activities:			
Net income (loss)	$ 2,050,484	$ (1,315,304)	$ (253,535)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation	1,643,014	1,538,102	1,407,963
Amortization	1,006,847	978,953	694,925
Stock based compensation	983,286	1,495,773	1,481,102
Deferred income taxes	650,209	(834,412)	(172,627)
Gain on disposal of property and equipment	(40,037)	—	—
Loss on sale of investment	128,997	—	—
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable, net	(2,260,106)	652,640	(1,481,287)
Inventories	1,426,371	(323,136)	409,967
Prepaid expenses and other current assets	(52,498)	(519,003)	228,520
Accounts payable	278,123	478,189	269,679
Income tax payable	(241,044)	614,218	265,874
Other current liabilities	362,594	(120,912)	267,041
Net cash provided by operating activities	5,936,240	2,645,108	3,117,622
Investing Activities:			
Purchase of property, plant and equipment	(1,519,437)	(1,756,285)	(1,763,869)
Proceeds from sale of property and equipment	79,227	—	—
Business acquisition, net of cash acquired	—	(15,057,816)	—
Patents, intangibles and goodwill	(265,423)	346,571	(65,882)
Purchases of marketable securities	(25,245,286)	(46,363,183)	(66,622,304)
Sales and maturities of marketable securities	44,899,761	51,101,714	65,683,722
Net cash provided by (used in) investing activities	17,948,842	(11,728,999)	(2,768,333)
Financing Activities:			
Proceeds from short-term debt	778,623	17,864,367	—
Increase in short-term debt	—	—	600,000
Payments on long-term debt	(18,640,808)	(2,643,415)	(1,765,124)
Excess tax benefit from exercises of stock options	—	—	39,979
Repurchase of common stock	(1,088,619)	(2,513,871)	(1,202,339)
Proceeds from issuance of common stock	180,291	646,917	40,942
Net cash provided by (used in) financing activities	(18,770,513)	13,353,998	(2,286,542)
Effect of exchange rate on cash and cash equivalents	83,859	(93,079)	117,576
Increase (decrease) in cash and cash equivalents	5,198,428	4,177,028	(1,819,677)
Cash and cash equivalents at beginning of year	8,722,935	4,545,907	6,365,584
Cash and cash equivalents at end of year	$ 13,921,363	$ 8,722,935	$ 4,545,907
Supplemental Cash Flow Information:			
Cash paid for interest	$ 164,178	$ 73,907	$ 109,779
Cash paid for income taxes	863,865	85,602	264,743

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

September 30, 2012

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 and intermittent catheters, and innovative and technologically advanced products such as its *FemSoft Insert* and antibacterial and hydrophilic intermittent catheters. Through fiscal 2012, the Company also manufactured and marketed a line of standard and advanced Foley 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 the purchase of Laprolan and related to annual impairment testing, deferred income taxes and stock-based compensation. Actual results could differ from those estimates.

2. Summary of Significant Accounting Policies

Statement of Presentation and Principles of Consolidation

The accompanying Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the Unites States of America ("U.S. GAAP"). References in this report to a particular fiscal year are to the twelve months ended September 30 of that year.

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 $7.7 million and $7.0 million at September 30, 2012 and 2011 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, 2012, the Company has $6.8 million invested in high quality, investment grade debt securities, primarily consisting of $6.3 million invested in U.S. treasury bills and $.5 million invested in CDs. At

September 30, 2011, the Company's marketable securities included $26.2 million invested in high quality, investment grade debt securities, 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. The Company reported an unrealized loss from the mutual fund of $.5 million at September 30, 2011. The mutual fund was liquidated in 2012 and a loss of $.1 million was realized.

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 Gain/(Loss)	Fair Value
September 30, 2012	$ 6,777,874	$ 1,821	$ 6,779,695
September 30, 2011	$26,641,059	$(458,751)	$26,182,308

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.

Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures*, establishes a framework for measuring fair value of financial assets and liabilities that are re-measured and reported 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 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 amount of the Company's long-term debt at September 30, 2011 approximated 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 on intangible assets was recognized in the fiscal years ended September 30, 2012, 2011 and 2010.

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, *Intangibles — Goodwill and Other*. 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 $4.3 million of goodwill carrying value as of September 30, 2012 resulting from its acquisition in the U.K. of Rochester Medical Limited in 2006 and $4.8 million 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 1st of each fiscal year for the goodwill associated with the Company's 2006 U.K. 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 impairment testing of the goodwill at June 1, 2012, and concluded that the goodwill was not impaired. In the third quarter of fiscal 2012, the Company did decrease the previously reported goodwill balance and deferred tax liabilities as of September 30, 2011 by $669,000 to record a deferred tax asset related to Laprolan that existed as of the acquisition date and which impacted purchase accounting and was treated as a correction of an immaterial error.

No impairment loss on goodwill was recognized in the fiscal years ended September 30, 2012, 2011 and 2010. The goodwill and intangible assets related to the Rochester Medical Limited and Laprolan B.V. acquisitions are accounted for in British pounds and euros, respectively. The decrease in value of goodwill as of September 30, 2012 compared to September 30, 2011 is due to the decrease in foreign currency exchange rates in the United Kingdom and the Eurozone.

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 on long-lived assets was recognized in the fiscal years ended September 30, 2012, 2011 and 2010.

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 the Company are recorded in certain non-U.S. functional currencies 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 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 as marketing and selling costs. The Company recorded such marketing and selling costs of $1,708,000, $1,690,000 and $1,216,000 for the years ended September 30, 2012, 2011 and 2010, respectively.

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 2012, the Company recorded a valuation allowance of $216,000 of which $42,000 is related to Minnesota R&D credit and $174,000 pertains to U.S. federal capital loss carryovers as the Company believes it is more likely than not that these deferred tax assets 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, 2012, 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.

Advertising Costs

The Company incurred advertising expenses of $1,353,000, $1,370,000 and $1,600,000 for the years ended September 30, 2012, 2011 and 2010, 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 $983,000, $1,496,000 and $1,481,000 ($639,000, $969,000 and $959,000 net of tax) of related stock-based compensation expense for the years ended September 30, 2012, 2011 and 2010, 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,		
	2012	2011	2010
Numerator:			
Net income (loss)	$ 2,050,484	$(1,315,304)	$ (253,535)
Denominator:			
Denominator for basic net income per common share — weighted average shares outstanding	12,032,113	12,217,900	12,181,549
Effect of dilutive stock options	307,387	—	—
Denominator for diluted net income per common share — weighted average shares outstanding	12,339,500	12,217,900	12,181,549

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. No shares were considered antidilutive for 2012. Average shares outstanding for diluted net income 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 (Loss)

The Company computes comprehensive income (loss) in accordance with ASC 220, *Comprehensive Income*. 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 2012 and 2011 was as follows:

	2012	2011
Unrealized gain (loss) on available-for-sale securities, net of tax	$ 1,821	$ (204,884)
Cumulative foreign currency translation	(3,924,191)	(3,910,993)
Accumulated other comprehensive loss	$(3,922,370)	$(4,115,877)

Legal Proceedings

The Company is 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 its financial condition, results of operations or cash flows.

Reclassifications and Revisions

The Company reclassified certain expenses from Marketing and Selling to General and Administrative in the fiscal 2011 financial statements to conform to the current year presentation. The Company also made revisions to the fiscal 2011 and 2010 financial statements to properly report shipping and handling fees and related costs. The reclassification and revisions are shown below but they had no impact on amounts previously reported for income (loss) from operations, income (loss) before income taxes, and net income (loss).

	As Previously Reported	Reclassification	Revision	As Reported
2011				
Net Sales	$52,918,875	$ —	$ 453,823	$53,372,698
Cost of Goods Sold	26,821,427	—	(97,481)	26,723,946
Marketing and Selling	18,966,887	(703,746)	551,304	18,814,445
General and Administrative	7,799,210	703,746	—	8,502,956
2010				
Net Sales	41,442,680	—	105,108	41,547,788
Cost of Goods Sold	21,739,014	—	(229,888)	21,509,126
Marketing and Selling	$11,868,737	$ —	$ 334,996	$12,203,733

New Accounting Pronouncements

In June 2011, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2011-05, "*Presentation of Comprehensive Income*" which requires comprehensive income to be reported in either a single statement or in two consecutive statements reporting net income and other comprehensive income. The amendment does not change what items are reported in other comprehensive income. Additionally, in December 2011, the FASB issued ASU No. 2011-12, "*Comprehensive Income (Topic 220): Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*" which indefinitely defers the requirement in ASU No. 2011-05 to present reclassification adjustments out of accumulated other comprehensive income by component in both the statement in which net income is presented and the statement in which other comprehensive income is presented. During the deferral period, the existing requirements in U.S. GAAP for the presentation of reclassification adjustments must continue to be followed. These standards will be effective for the Company's fiscal quarter beginning October 1, 2012 with retrospective application required. As these standards impact presentation requirements only, the adoption of this guidance will not have an impact on the Company's results of operations or financial position.

In September 2011, the FASB issued ASU No. 2011-08, *"Testing Goodwill for Impairment"* that is intended to simplify how entities test goodwill for impairment. This ASU permits an entity to first assess qualitative factors to determine whether it is "more likely than not" that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test described in ASC Topic 350, "*Intangibles — Goodwill and Other*". This update is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 (the Company's fiscal 2013). This standards update is not expected to have a material impact on the Company's 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 with its second quarter of fiscal 2011. 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 fair values of the assets and liabilities acquired at the date of acquisition. Included in the intangible assets acquired was approximately $5,602,000 of goodwill and $5,612,000 of finite-lived intangibles. In the third quarter of fiscal 2012, the intangible assets and long-term liabilities were adjusted by $669,000 to record a deferred tax asset related to Laprolan that existed as of the acquisition date and which impacted purchase accounting and was treated as a correction of an immaterial error.

Current assets	$ 3,212,000
Property and equipment	1,831,000
Intangible assets	10,545,000
Total assets acquired	$15,588,000
Current liabilities	$ 824,000
Long term liabilities	877,000
Total liabilities assumed	$ 1,701,000

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	
	2011	2010
Net sales	$55,633	52,767
Net income (loss)	(159)	2,356
Per share data:		
Basic income (loss)	$ (.01)	$ 0.19
Diluted income (loss)	$ (.01)	$ 0.18

In the table above for the year ended September 30, 2011, $725,000 has been added back to net loss for one-time merger and acquisition costs and $45,000 has been added back to net loss 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. Inventories

Inventories are summarized as follows:

	September 30,	
	2012	2011
Raw materials	$1,301,145	$ 1,548,095
Work-in-process	3,251,644	3,598,623
Finished goods	5,330,862	6,131,976
Totals	$9,883,651	$11,278,694

5. Intangible Assets

Intangible assets were as follows:

		September 30, 2012			September 30, 2011		
	Estimated Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net Value	Gross Carrying Amount	Accumulated Amortization	Net Value
Trademarks	8 to 15	$ 6,168,758	$2,736,004	$3,432,754	$ 5,958,480	$2,187,663	$ 3,770,817
Supply agreement	5 to 6.5	762,579	634,050	128,529	767,870	628,357	139,513
Customer relationships	15 to 20	6,888,864	1,258,420	5,630,444	7,017,938	866,613	6,151,325
Totals		$13,820,201	$4,628,474	$9,191,727	$13,744,288	$3,682,633	$10,061,655

Amortization expense related to these assets was as follows:

Year ended September 30, 2012	$945,841
Year ended September 30, 2011	934,890
Year ended September 30, 2010	633,335

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

2013	$899,000
2014	868,000
2015	805,000
2016	805,000
2017	800,000

6. 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 2015. In the normal course of business, it is expected that these leases will be replaced by leases on other vehicles as the lease terms expire.

Lease expense totaled approximately $778,000, $724,000 and $378,000 during fiscal 2012, 2011 and 2010, respectively.

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

2013	$646,000
2014	546,000
2015	257,000

7. Shareholders' Equity

Equity-Based Awards

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, 2012, there were 1,083,500 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. As of September 30, 2012, 346,627 shares of common stock remain available for issuance under the 2010 Stock Incentive Plan.

The Company measures stock-based compensation cost at the grant date based on the fair value of the award and recognizes the compensation expense over the requisite service period, which is generally the vesting period.

Restricted stock

The fair value of restricted stock awards was calculated using the Company's stock price as of the associated grant date, and the expense is accrued ratably over the vesting period of the award.

Compensation expenses associated with restricted stock awards for years ended September 30, 2012 and 2011, totaled $237,000 and $59,000, respectively. At September 30, 2012, unamortized compensation cost of restricted stock awards totaled $629,000. The unamortized cost is expected to be recognized over a weighted-average period of 2.5 years as of September 30, 2012.

A summary of restricted shares activity under the Plans as of September 30, 2012 and 2011, and changes during the years then ended is presented below:

Restricted Shares	Shares	Weighted Average Grant Date Fair Value
Unvested balance at September 30, 2010	40,000	$11.77
Granted	40,000	10.99
Vested	(40,000)	11.77
Forfeited	—	—
Unvested balance at September 30, 2011	40,000	10.99
Granted	61,883	7.86
Vested	—	—
Forfeited	(2,000)	7.86
Unvested balance at September 30, 2012	99,883	$ 9.11

Restricted stock units

In fiscal 2012, the Company issued 135,491 restricted stock units (RSUs) to its executive management team. The fair value of the RSUs was calculated using the Company's stock price, $7.86 per unit, at the date of grant. The RSUs include a performance-based vesting trigger measured in fiscal 2013, and the Company did not recognize any compensation expense associated with the RSUs for the year ended September 30, 2012.

Stock options

The Company accounts for stock option-based compensation by estimating the fair value of options granted using a Black-Scholes option valuation model. The Company recognizes the expense for grants of stock options on a straight-line basis in the statement of operations as operating expense based on their fair value over the requisite service period.

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-option awards with the following weighted-average assumptions for the year ended September 30, 2011. There were no stock option awards issued for the year ended September 30, 2012.

	2012	2011
Dividend yield	n/a	0%
Expected volatility	n/a	47%
Risk-free interest rate	n/a	3.42%
Expected holding period (in years)	n/a	8.74
Weighted-average grant-date fair value	n/a	$6.29

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 Company has not paid, and does not anticipate, dividend payments.

The weighted average fair value of options granted in 2011 was $6.29 per share.

A summary of option activity under the Plans as of September 30, 2012 and 2011, and changes during the years then ended is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Outstanding at September 30, 2010	1,632,700	$ 8.03	—	
Granted	230,000	10.72		
Exercised	(273,950)	2.36		
Forfeited	—	—		
Outstanding at September 30, 2011	1,588,750	$ 9.39	5.8	$1,464,000
Granted	—	—		
Exercised	(69,250)	2.60		
Forfeited	(18,000)	10.96		
Outstanding at September 30, 2012	1,501,500	$ 9.69	5.1	$3,425,000
Exercisable at September 30, 2012	1,249,750	$ 9.36	4.6	$3,266,000
Exercisable at September 30, 2011	1,160,625	$ 8.68	4.9	$1,464,000

The Company recorded compensation expense of stock options of $746,000, $1,437,000 and $1,481,000 for the years ended September 30, 2012, 2011 and 2010, respectively. As of September 30, 2012, there was $467,000 of total unrecognized compensation cost related to unvested stock option based compensation arrangements granted under the Plans. The unamortized cost is expected to be recognized over a weighted-average period of 1.4 years as of September 30, 2012.

The Company issues new shares as settlement of options exercised. Cash received from option exercises for the years ended September 30, 2012, 2011 and 2010 was $180,000, $647,000, and $41,000, respectively. The intrinsic value of shares exercised was $273,000, $2,192,000 and $52,800, for the years ended September 30, 2012, 2011 and 2010, respectively.

8. Income Taxes

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

	September 30,	
	2012	2011
Deferred income tax assets:		
Allowance for doubtful accounts	$ 29,000	$ 15,000
Inventory reserves	44,000	57,000
Inventory capitalization	289,000	450,000
Accrued expenses	127,000	94,000
Nonqualified option expense	1,824,000	1,648,000
Restricted stock expense	109,000	17,000
Capital loss carryforward	174,000	39,000
Charitable contributions	59,000	58,000
Research and development credits	136,000	71,000
Net operating loss	606,000	1,095,000
ASC 320 unrealized loss	—	202,000
Valuation allowance	(216,000)	(42,000)
Total income tax deferred assets	3,181,000	3,704,000
Deferred income tax liability:		
Depreciation and amortization	1,957,000	1,684,000
Net deferred income tax assets	$1,224,000	$2,020,000

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

	September 30,	
	2012	2011
Current assets	$ 1,287,177	$ 1,618,495
Noncurrent assets	1,030,994	1,242,010
Noncurrent liabilities	(1,093,717)	(840,512)
	$ 1,224,454	$ 2,019,993

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 2012, the Company recorded a valuation allowance of $216,000 related to Minnesota R&D credit and U.S. federal capital loss carryovers as the Company believes it is more likely than not that these deferred tax assets 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, 2012, 2011, and 2010 consist of the following:

	September 30,		
	2012	2011	2010
Income (loss) before taxes:			
U.S.	$ 257,703	$(3,565,971)	$ 584,963
Non-U.S.	2,824,585	1,627,505	(314,634)
Total income (loss) before taxes	3,082,288	(1,938,466)	270,329
Provision (benefit) for taxes:			
U.S.			
Current tax expense (benefit)	163,335	(142,766)	551,779
Deferred tax expense (benefit)	242,852	(946,530)	609
Total U.S.	406,187	(1,089,296)	552,388
Non-U.S.			
Current tax expense	229,998	425,820	—
Deferred tax expense (benefit)	395,619	40,314	(28,524)
Total Non-U.S.	625,617	466,134	(28,524)
Total provision (benefit) for taxes	$1,031,804	$ (623,162)	$ 523,864

The reconciliation between the statutory federal income tax rate and the effective income tax rate for the years ended September 30, 2012, 2011 and 2010 is as follows:

	2012	2011	2010
Statutory federal income tax rate	34%	34%	34%
Increase (decrease) in taxes resulting from:			
State taxes	6	3	4
Foreign taxes	(12)	11	31
Meals and entertainment	2	(2)	6
Acquisition costs	—	(9)	—
Incentive stock options	4	(9)	66
Change in valuation allowance and utilization of net operating loss carryforward	4	—	17
R&D credits	(2)	1	(15)
Return to provision and true up adjustments	1	(2)	46
Change in reserves	(1)	1	(4)
Rate adjustment on deferred taxes	(2)	7	18
DPAD	—	—	(10)
Other	—	(3)	1
Effective income tax rate	34%	32%	194%

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, 2012, the Company has recognized approximately $43,000 for unrecognized tax benefits. If the Company were to prevail on all unrecognized tax benefits recorded at September 30, 2012, the total gross unrecognized tax benefit totaling approximately $43,000 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, 2012, 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, 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 October 1, 2011	55,902
Increases/(decreases) as a result of tax positions taken during a prior period	3,997
Increases/(decreases) as a result of expiration of jurisdiction statutes of limitations	(21,444)
Increases/(decreases) as a result of tax positions taken during the current period (including interest)	5,040
Balance at September 30, 2012	$ 43,495

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.

9. Significant Customers

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

	September 30,		
	2012	2011	2010
Significant customers:			
Hollister	9%	9%	10%
Coloplast and Coloplast subsidiaries	9	10	14
Total	18%	19%	24%

10. 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, 2012, 2011 and 2010 was approximately $154,000, $149,000 and $134,000 respectively. The Company also makes contributions to the Group Personal Pension Scheme for the benefit of the employees of its U.K. and Laprolan B.V. subsidiaries. The total contributions for the years ended September 30, 2012, 2011 and 2010 were approximately $252,000, $165,000 and $65,000, respectively.

11. Geographic Area Data

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

	September 30,		
	2012	2011	2010
Sales:			
United States	$22,922,000	$18,717,000	$16,888,000
United Kingdom	21,166,000	18,296,000	15,120,000
The Netherlands*	8,646,000	7,345,000	432,000
Europe & Middle East**	7,901,000	7,976,000	8,139,000
Rest of world	1,048,000	1,039,000	969,000
Total	$61,683,000	$53,373,000	$41,548,000

* 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,	
	2012	2011
Long-lived assets:		
United States	$ 8,689,000	$ 8,762,000
United Kingdom	1,363,000	1,326,000
The Netherlands	1,810,000	1,965,000
Total	$11,862,000	$12,053,000

12. 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%, which reflected the Company's cost of borrowing at the date of the purchase agreement and the discount was amortized over the life of the note. 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. In conjunction with the closing of the Laprolan acquisition described under Note 3, on April 7, 2011, the Company drew down $15,057,775 from the line of credit. In January 2012, the Company used a portion of its cash and cash equivalents and marketable securities and paid off its entire outstanding balance on its line of credit. The borrowings under this credit facility are limited to the value of eligible assets held with RBC Wealth Management. The credit facility now consists of a revolving line of credit of up to $5,000,000 with interest accruing monthly at a variable rate of 1.375% as of September 30, 2012. As of September 30, 2012, the Company had no outstanding balance under the revolving line of credit.

13. 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, 2012, the Company did not repurchase any shares. During fiscal 2012, the Company repurchased 150,900 shares of common stock pursuant to this program at an average price of $7.21 per share. Total cash consideration for the repurchased shares was $1,089,000. As of September 30, 2012, there remained 1,278,947 shares that may be purchased under the program.

14. Subsequent Events

Through the Company's fiscal year ended September 30, 2012, the Company's urological products included a line of Foley catheters targeted to the acute care market under the *Rochester Medical* brand and under private label arrangements. In November 2012, the Company announced its decision to cease manufacturing and marketing Foley catheters and focus on its core product lines of MECs and intermittent catheters.

15. Quarterly Results (Unaudited)

Summary data relating to the results of operations for each quarter of the years ended September 30, 2012 and 2011 follows (in thousands, except per share amounts):

	Three Months Ended			
	December 31	March 31	June 30	September 30
Fiscal year 2012:				
Net sales	$13,973	$15,428	$15,385	$16,897
Gross profit	7,111	7,605	7,625	8,477
Income (loss) from operations	(21)	834	713	1,687
Net income (loss) before taxes	(112)	884	735	1,575
Net income (loss) per common share — basic	$ (.01)	$ .05	$ .04	$ .09
Net income (loss) per common share — diluted	$ (.01)	$ .05	$ .04	$ .08
Fiscal year 2011:				
Net sales	$10,999	$12,942	$14,413	$15,019
Gross profit	5,499	6,457	7,129	7,564
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

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

None.

ITEM 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (the "Evaluation") at a reasonable assurance level as of the last day of the period covered by this Report.

Disclosure controls and procedures are defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act") as controls and other procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified by the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

It should be noted that the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions, regardless of how remote.

Based upon the Evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective at a reasonable assurance level as of the last day of the period covered by this Report. As noted below, we have identified a material weakness in our internal controls over financial reporting related to our accounting policy for shipping and handling fees and related costs. The principal factor that contributed to this material weakness was the misinterpretation of accounting standards related to the classification of shipping and handling fees and related costs pursuant to ASC 605-45-45-20 and ASC 605-45-50-2, "Shipping and Handling Fees and Costs."

Management's Annual 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. Our management assessed the effectiveness of our internal control over financing reporting as of September 30, 2012. 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 this assessment, our management believes that as of September 30, 2012, our internal control over financial reporting was not effective based on those criteria.

Based on our assessment, management believes that, as of September 30, 2012, our internal control over financial reporting was not effective due to the identification of a material weakness related to our policy and review controls over the accounting for shipping and handling fees and related costs. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Grant Thornton LLP, an independent registered public accounting firm, has audited the Consolidated Financial Statements included in this Annual Report on Form 10-K and, as part of its audit, has issued an attestation report, included herein, on the effectiveness of our internal control over financial reporting.

Planned Remediation Efforts to Address Material Weakness

As stated above, we identified a material weakness in our controls over the accounting for shipping and handling fees and related costs. This error was identified during the quarter ended September 30, 2012. The principal factor that contributed to this material weakness was the misinterpretation of accounting standards related to the classification of shipping and handling fees and related costs pursuant to ASC 605-45-45-20 and ASC 605-45-50-2, "Shipping and Handling Fees and Costs" and that the misinterpretation was not identified in our review of the financial statement reporting disclosures.

This material weakness resulted in a number of classification errors in our reporting for shipping and handling fees and related costs and required certain revisions of our shipping and handling fees and related costs between net sales, cost of sales, and marketing and selling expenses in our Annual Report on Form 10-K for the fiscal year ended September 30, 2012.

To remediate the material weakness described above, we have implemented remedial measures including a review of all of our shipping and handling transactions to correct instances where we were not complying with generally accepted accounting principles. In addition, we have developed updated procedures to reflect the applicable technical guidance pertaining to accounting for shipping and handling fees and related costs and have instituted additional management review to confirm the proper implementation of accounting standards going forward. Despite the remedial measures that have been implemented, the material weakness cannot be considered remediated until the applicable remedial controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

We currently expect that the necessary testing of the controls over accounting for shipping and handling costs to remediate the finding will be completed in fiscal 2013.

Changes in Internal Control Over Financial Reporting

Except as otherwise discussed above, there were no changes in our internal control over financial reporting that have materially affected or are reasonably likely to materially affect such controls, including any corrective actions with regard to significant deficiencies and material weaknesses.

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, 2012, 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, 2012, (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, 2012:

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)	1,636,991	$9.69	346,627
Equity compensation plans not approved by security holders	—	—	—
Total	1,636,991	$9.69	346,627

(1) Includes shares issuable under our 2001 Stock Incentive Plan and 2010 Stock Incentive Plan. Also includes 135,491 performance-based restricted stock units (RSUs) issuable under our 2010 Stock Incentive Plan that, upon vesting, become the right to receive shares. For purposes of column (a), the number of shares to be issued under a performance-based RSU reflects the maximum number of shares of our common stock that may be issued pursuant to such RSU. Such RSUs do not have an exercise price and are not included in column (b).

(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, 2012, 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, 2012, 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, 2012, 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, 2012 and 2011.

(ii) Consolidated Statements of Operations for the years ended September 30, 2012, 2011 and 2010.

(iii) Consolidated Statement of Shareholders' Equity and Comprehensive Income (Loss) for the years ended September 30, 2012, 2011 and 2010.

(iv) Consolidated Statements of Cash Flows for the years ended September 30, 2012, 2011 and 2010.

(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 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).

10.12† The Company's Fiscal 2012 Management Incentive Plan. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on December 9, 2011).

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 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)

10.19† Form of 2010 Stock Incentive Plan Restricted Stock Award Agreement for employees. (Incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on January 30, 2012)

10.20† Form of 2010 Stock Incentive Plan Restricted Stock Award Agreement for directors. (Incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed on January 30, 2012)

10.21†	Form of 2010 Stock Incentive Plan Restricted Stock Unit Award Agreement for employees. (Incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed on January 30, 2012)
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, 2012, 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 19, 2012

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
* Peter H. Shepard	Director
* Benson Smith	Director
*By David A. Jonas David A. Jonas *Attorney-in-Fact*	Dated: December 19, 2012

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

COL. A	COL. B	COL. C		COL. D	COL. E
		Additions		(1)	
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, 2012:					
Reserves and allowances deducted from asset accounts:					
Allowance for doubtful accounts	$44,595	$68,578	—	$26,905	$86,268
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

(1) Uncollectible accounts written off net of recoveries

INDEX TO EXHIBITS

Exhibit	
21	Subsidiaries of the Company.
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24	Power of Attorney
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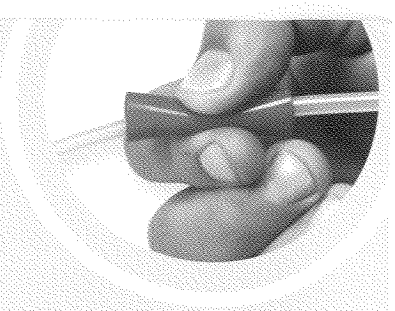
NEW ADVANCES IN

CONTROL

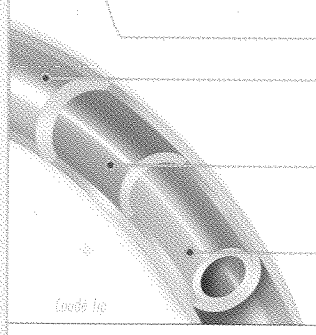


magic³™

INTERMITTENT CATHETER
with m³ technology

The Magic³ catheter is the only intermittent catheter to offer touch-free insertion and maximum control, without sacrificing comfort.

- GENTLE ON SENSITIVE TISSUE
- EASY HANDLING
- OPTIMAL DRAINAGE FLOW



Ultra-Soft Outer Layer
to maximize comfort

Firm Middle Layer
for easy handling

Pliable Innermost Layer
for easy navigation

NEW COUDÉ TIP: *a specially-designed curved tip designed to aid in insertion, especially around natural curves within the urethra.*

magic³®

INTERMITTENT CATHETER
with Sure-Grip™

NO TOUCH INSERTION:

This innovative insertion sleeve provides touch-free insertion while allowing the user to firmly grip the slippery catheter surface, making it easier to maneuver and minimizing the risk of contamination.

Now available in straight tip and our new coudé tip.

*Greater **INDEPENDENCE**, **COMFORT**, and **CONFIDENCE** for people needing intermittent catheterization.*

INTRODUCING A NEW OUTLOOK

in continence care

SPIRIT™

HYDROCOLLOID ADHESIVE SHEATH

By leveraging advanced proprietary hydrocolloid technology, Rochester Medical developed Spirit™ Hydrocolloid Adhesive Sheath, the next generation of male external catheters.

Spirit is the first and only self-adhering male sheath to combine the superior moisture-wicking properties of a hydrocolloid adhesive with the unmatched breathability of silicone.

ADVANCED FEATURES:

- HYDROCOLLOID ADHESIVE
  Wicks away moisture, protecting skin integrity
- ALL-SILICONE CONSTRUCTION
  Provides superior breathability and conforms to body contours
- TRANSPARENT MATERIAL
  Permits continuous skin monitoring
- KINK-RESISTANT DESIGN
  Ensures continuous flow
- SELF-ADHERING
  No need for tape or straps
- ADHESIVE PLACEMENT
  Minimizes urine buildup
- LATEX-FREE
  No latex-associated allergic reactions

UNMATCHED PERMEATION ▶ *Water vapor transmission rates for male external catheters (gm/M2/24 hrs)*

226	150	31	10
Spirit: Silicone sheath with hydrocolloid adhesive	Silicone sheath with standard adhesive	Latex sheath with standard adhesive	Non-latex, non-silicone sheath with standard adhesive

Rochester MEDICAL

2012

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.

Peter H. Shepard: Chairman of the Auxiliary Ambassador Committee at Santa Barbara Cottage Hospital and past President of the hospital auxiliary. He is a member of the Society of Urologic Nurses and Associates, the Association of Rehabilitation Nurses and the International Continence Society. He has also held a number of sales and marketing and business development positions in the Urology and Urogynecology division at Mentor Corporation, retiring as Senior Vice-President Global Sales & Marketing and Business Development.

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
Sarah L. Grinde: Vice President, Development & Research
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 Agents:
Wells Fargo Shareowner Services
1110 Centre Pointe Curve, Suite 101
Mendota Heights, Minnesota 55120 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 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
FQ 2012	**Quarter 1**	**Quarter 2**	**Quarter 3**	**Quarter 4**
Fiscal High	$8.30	$10.10	$10.90	$12.45
Fiscal Low	$6.68	$7.45	$9.46	$9.93

Form 10-K Availability:
Copies of the Company's Form 10-K for the 2012 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

EXPANSION

BREAKING **NEW GROUND** IN 2013

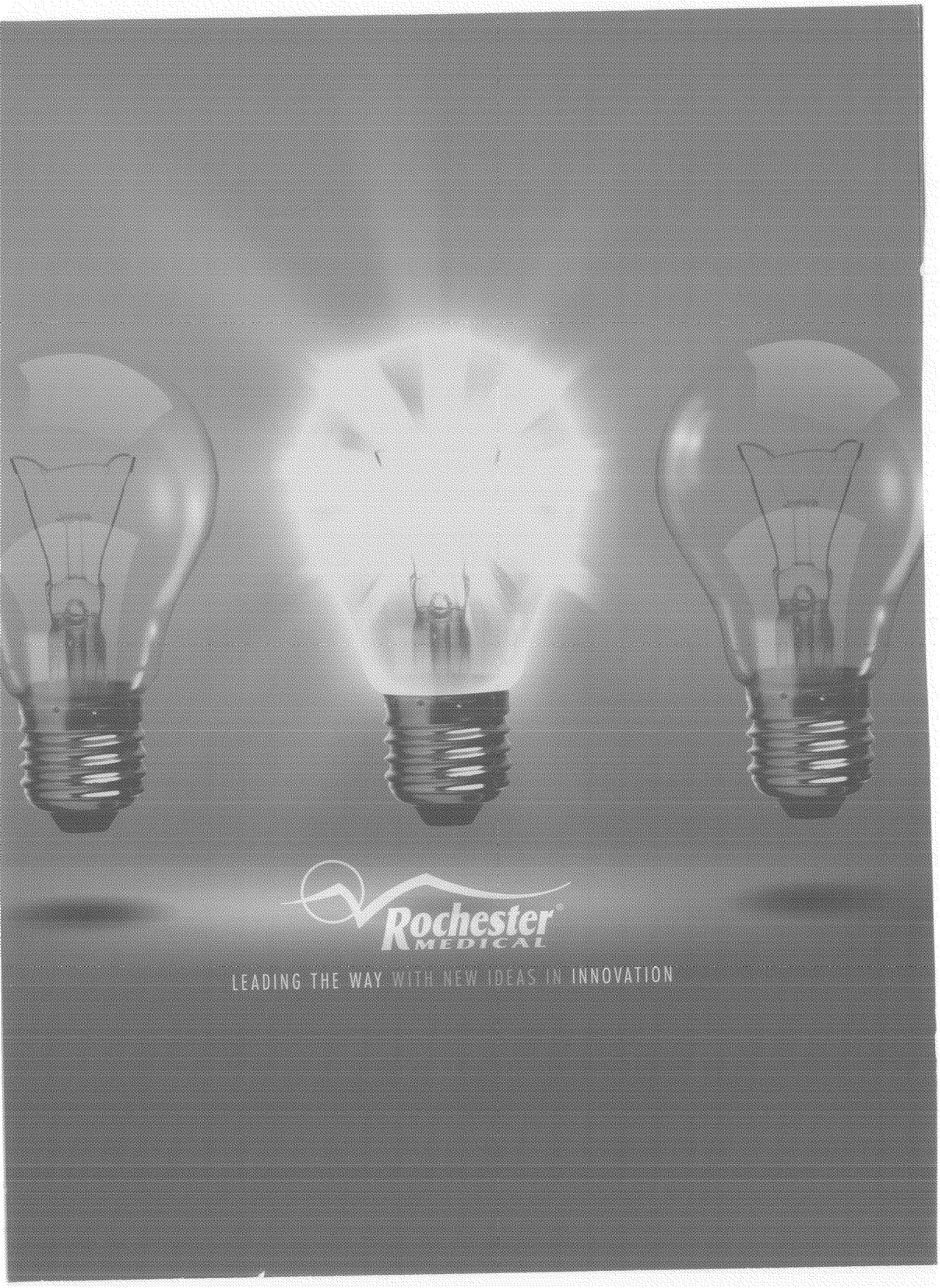
Rochester Medical has recently broken ground to establish a new, state-of-the-art production facility on our main campus in Stewartville, MN. The new 54,000 square foot building will provide increased capacity for current products and feature highly sophisticated automation and robotics systems as well as provide the opportunity to implement new and innovative processes supporting future technological advancements.

"We are very excited to begin this new construction project. This facility will allow us to bring new, technologically advanced products to the market and continue in the spirit of innovation in which Rochester Medical was founded."

SARAH L. GRINDE: *Vice President, Development & Research*

Rochester MEDICAL

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


Rochester
MEDICAL
LEADING THE WAY WITH NEW IDEAS IN INNOVATION