UROPLASTY INC
Form 10-K
May 24, 2012

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 the Fiscal Year Ended March 31, 2012

Commission File No. 001-32632

UROPLASTY, INC.
(Exact name of registrant as specified in its Charter)

Minnesota	41-1719250
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

5420 Feltl Road
Minnetonka, Minnesota 55343
(Address of principal executive offices)

(952) 426-6140
(Issuer's telephone number, including area code)

Securities registered under Section 12(b) of the Exchange Act:

Title of class	Name of Exchange on which registered
Common Stock, $.01 par value	NASDAQ

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES o NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.
YES o NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or 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 x NO o

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 (§

229.405 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 x NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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. x

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

Large Accelerated Filer ¨ Accelerated Filer x 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 o NOx

The aggregate market value of the voting stock and nonvoting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of September 30, 2011 was $85,630,295.

As of May 24, 2012 the registrant had 20,808,532 shares of common stock outstanding.

Documents Incorporated By Reference: Portions of our Proxy Statement for our 2011 Annual Meeting of Shareholders (the "Proxy Statement"), are incorporated by reference in Part III.

TABLE OF CONTENTS

Table of Contents

FORWARD LOOKING STATEMENTS

This Form 10-K contains "forward-looking statements" relating to projections, plans, objectives, estimates, and other statements of future performance. These forward-looking statements are subject to known and unknown risks and uncertainties relating to our future performance that may cause our actual results, performance, achievements, or industry results, to differ materially from those expressed or implied in any such forward-looking statements. Our business operates in highly competitive markets and our operating results and the achievement of the forward-looking statements may be impacted by changes in general economic conditions, competition, reimbursement levels, customer and market preferences, government regulation, tax regulation, foreign exchange rate fluctuations, the degree of market acceptance of products, the uncertainties of potential litigation, and other matters detailed in the "Risk Factors" contained in Item IA of this report.

We do not undertake nor assume any obligation to update any forward-looking statements that we may make from time to time.

PART I

Item 1. Description of Business

Overview

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. You can access, free of charge, our filings with the Securities and Exchange Commission, including our annual report on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any other amendments to those reports, at our website www.uroplasty.com, or at the Commission's website at www.sec.gov.

Our primary focus is on two products: the Urgent PC® Neuromodulation System, which we believe is the only FDA-cleared minimally invasive neuromodulation system that delivers percutaneous tibial nerve stimulation (PTNS) for office-based treatment of overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence; and Macroplastique® Implants, an injectable urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency (ISD). Outside of the U.S., our Urgent PC System is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence, fecal incontinence, vocal cord rehabilitation and vesicoureteral reflux.

Our primary focus is on growth in the U.S. market, which we entered in 2005 with our Urgent PC System. Prior to that time, essentially all of our business involved the sale of Macroplastique and other products outside of the U.S. We believe the U.S. market presents a significant opportunity for growth in sales of our products.

The Urgent PC Neuromodulation System uses percutaneous stimulation to deliver to the tibial nerve electrical pulses that travel to the sacral nerve plexus, a control center for bladder function. We have received regulatory clearances for

sale of the Urgent PC System in the United States, Canada and Europe. We launched sales of our second generation Urgent PC System in late 2006. We have intellectual property rights relating to key aspects of our neuromodulation therapy.

We have sold Macroplastique for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from the FDA pre-market approval for the use of Macroplastique to treat adult female stress urinary incontinence. We began marketing Macroplastique in the United States in 2007.

We believe physicians prefer our products because they offer effective therapies for patients that can be administered in office- or outpatient surgical-based settings and, to the extent reimbursement is available, provide the physicians a profitable revenue stream. We believe patients prefer our products because they are minimally invasive treatment alternatives that do not have the side effects associated with pharmaceutical treatment options nor the morbidity associated with surgery.

Developments

Our sales during the past four years have been significantly influenced by the availability of third-party reimbursement for PTNS treatments. Sales of our Urgent PC System grew rapidly during fiscal 2007 and 2008 with rapid market acceptance of PTNS treatments that were reimbursed under a Current Procedure Technology (CPT®) code. However, during the first quarter of fiscal 2009 the American Medical Association (AMA) advised the medical community that the previously recommended Category 1 CPT code for reimbursement for PTNS treatments should be replaced with an unlisted CPT code. As a result, many third-party insurers delayed or denied reimbursement for PTNS treatments, and sales of our Urgent PC System in the U.S. declined from a peak of $2.2 million in the first quarter of our fiscal 2009 to a range of $0.9 million to $1 million per quarter in the six subsequent fiscal quarters ended December 2010.

Table of Contents

We responded by sponsoring several randomized, controlled clinical studies over the following two years, and supported by publication of these clinical studies in U.S. peer-reviewed journals, we applied for, and effective January 2011 the AMA granted, a Category 1 CPT code for PTNS treatments. The AMA advised us of this decision prior to the effective date and we began to expand our sales organization in anticipation of increased interest in our Urgent PC. We have expanded our U.S. field sales and support organization from 15 employed sales representatives and six independent manufacturer's representatives on April 1, 2010 to 39 employed sales representatives and one independent manufacturer's representative on March 31, 2012.

We also focused our efforts on expanding reimbursement coverage with the Medicare carriers and private payers by instituting a comprehensive program to educate their medical directors regarding the clinical effectiveness, cost effectiveness and patient benefits of PTNS treatments using our Urgent PC System. As of March 31, 2012, ten regional Medicare carriers representing 35 states, with approximately 31 million covered lives, provide coverage for PTNS treatments. In addition, we estimate that private payers providing insurance to approximately 84 million lives provide coverage for PTNS treatments.

With the availability of a CPT Category 1 code and expanded reimbursement coverage from third-party payers, as well as an expanded sales organization, our U.S. Urgent PC sales of $7.8 million in the year ended March 31, 2012 grew 84% over sales during the year ended March 31, 2011. In addition, because of the discontinuation in the marketplace of a competing product and our expanded sales organization, sales of our Macroplastique product in the U.S. of $5.9 million in the year ended March 31, 2012 grew 69% over sales during the year ended March 31, 2011.

At March 31, 2012, three regional Medicare carriers representing 15 states, with approximately 17 million covered lives, continued to decline reimbursement coverage for PTNS treatments. We participated during fiscal 2012 with two Medicare beneficiaries who filed administrative appeals for reconsideration of the decisions of two of those regional Medicare carriers. In April 2012, one of those two regional Medicare carriers, with 4.6 million covered lives, retired its negative coverage decision, and subsequently in May 2012 published their decision to provide coverage for PTNS treatments retroactive to April 9, 2012. The second appeal remains pending. We also understand that in calendar 2012, and as part of the plans announced by the Centers for Medicare and Medicaid Services to consolidate the regional carriers, two regional Medicare carriers currently reimbursing for PTNS treatments are expected to be consolidated into the regional Medicare carrier that recently retired its negative policy.

The Centers for Medicare and Medicaid Services expects to continue to consolidate the regional Medicare claims administrators and there is no guarantee that Medicare beneficiaries in a region with reimbursement coverage will continue to be reimbursed when consolidated into a regional Medicare carrier with a negative reimbursement policy, or, if reimbursed, the coverage would remain unchanged. We continue to work with the medical directors of both Medicare and private payers to expand coverage of PTNS treatments, and to ensure that coverage continues after the number of Medicare regions is decreased and regional Medicare administrators are transitioned.

We expect to further expand our U.S. field sales organization in the future, primarily to grow our U.S. Urgent PC sales. We do not expect to see significant growth in our U.S. Macroplastique business. The ultimate size of the field sales organization and the pace of expansion will depend upon the pace of market acceptance and expansion of third-party reimbursement coverage of our Urgent PC System.

Market

Neuromodulation Market

Neuromodulation therapy, which uses a low-voltage electrical current to treat medical conditions affecting parts of the nervous system, has grown dramatically in recent years. FDA-cleared neuromodulation devices are currently utilized

to treat a range of indications, including voiding dysfunctions, chronic pain, epilepsy, essential tremor, Parkinson's disease, hearing loss and depression. These devices are implanted in the body or used in a non-invasive manner to stimulate parts of the nervous system, including the spinal cord, sacral nerves, tibial nerve and vagus nerve, among other areas. We believe the neuromodulation market represents a significant opportunity for us in the treatment of OAB and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

Table of Contents

Voiding Dysfunction Market

Voiding dysfunctions affect urinary or bowel control and can result in uncontrolled bladder sensations (overactive bladder) or unwanted leakage (urinary or bowel/fecal incontinence). Urinary incontinence is defined as the involuntary loss of urine, and is a very common health problem, especially among women. In 2007, the US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases reported that, depending on the definition of urinary incontinence used, 5% to 50% of the adult U.S. population suffers from some form of urinary incontinence. The prevalence of urinary incontinence increases with advancing age, and the prevalence of U.S. population with urinary incontinence is expected to grow over the next decades as the U.S. population ages. Urinary incontinence often results in social isolation, depression, and poor self-rated health and quality of life, and is a significant medical condition with considerable public health impact.

When patients seek treatment for voiding dysfunction, physicians generally assess the severity of the symptoms as mild, moderate or severe. Regardless of the degree of severity, physicians usually first prescribe conservative therapy such as dietary changes, fluid management, bladder habit changes and pelvic floor muscle therapy. Because most patients do not respond to this conservative therapy, physicians often next prescribe anticholinergic drugs. For patients with the most severe conditions, and for the many patients who cannot tolerate the side effects of the drugs, the remaining options have historically been surgical intervention or surgical implantation of a sacral nerve stimulation device. We believe that with our Urgent PC System, an office-based, minimally invasive treatment solution, we are uniquely positioned to serve the many patients who find these other treatment options unsatisfactory, including the up to about 80% of the patients who discontinue drugs within one year due to poor efficacy or intolerance of side effects.

We believe that over the next several years a number of key demographic and technological factors will accelerate growth in the market for medical devices to treat OAB and other urinary and bowel voiding dysfunctions. These factors include the following:

Technology advances and patient awareness. Patients often weigh the clinical benefits, adverse side effects and the level of invasiveness of the procedures, along with other factors, in choosing a treatment alternative. In recent years, with the publicity associated with new technology and minimally invasive treatment alternatives, we believe the number of patients visiting physicians to seek treatment for voiding dysfunctions has increased. As a result, we believe more patients will choose to avoid drug therapy or, because of adverse side effects, choose to discontinue drug therapy for other alternatives which more simply and effectively manage their disorder.

Emphasis on quality of life. Patients have placed an increased emphasis on quality of life issues and maintaining active lifestyles. Their desire to improve their quality of life is usually an important factor in selecting a treatment for their disorder. We believe patients seeking treatment are increasingly considering alternatives designed to balance the therapeutic effect with any associated side effects. As a result, we believe patients will increasingly choose minimally invasive surgical treatments or other effective treatments such as neuromodulation.

Aging population. The number of individuals developing voiding dysfunctions will increase as the population ages and as life expectancies rise.

Overactive Bladder

Symptoms

For individuals with overactive bladder symptoms, the nervous system control for bladder filling and urinary voiding is incompetent. Signals to indicate a full bladder are sent early and frequently, triggers to allow the bladder to relax for filling are ineffective and nervous control of the urethral sphincter, to keep the bladder closed until an appropriate time, is inadequate. An individual with OAB may exhibit one or all of the symptoms that characterize overactive bladder: urinary urgency, urinary frequency and urge incontinence. Urgency is the strong, compelling need to urinate and frequency is a repetitive need to void. For most individuals, normal urinary voiding is about eight times per day while individuals with OAB may seek to void over 20 times per day and more than two times during the night. Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate that typically results in an accident before the individual can reach a restroom.

Treatment of Symptoms

Biofeedback and Behavioral Modification. Bladder training and scheduled voiding techniques, often accompanied by the use of voiding diaries, are non-invasive approaches to managing OAB. These techniques are seldom completely effective because they rely on the diligence of and compliance by the individual. In addition, these techniques may not affect the underlying cause of the condition.

Table of Contents

Drug Therapy. The most common treatment for OAB is drug therapy using an anticholinergic agent. However, for many patients drugs are ineffective or the side effects so bothersome that they discontinue the medications. Common side effects include dry mouth, dry eyes, constipation, cognitive changes and blurred vision.

Neuromodulation. Normal urinary control is dependent upon properly functioning neural pathways and coordination among the central and peripheral nervous systems, the nerve pathways, the bladder and the sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to OAB symptoms. Therapy using neuromodulation incorporates electrical stimulation to target specific neural tissue and "jam" the pathways transmitting unwanted signals. To alter bladder function, stimulation must be delivered to the sacral nerve plexus, which innervates the bladder and pelvic floor. Neuromodulation to treat OAB may be performed by a surgically implanted sacral nerve stimulation device or performed in a physician's office by the non-surgical PTNS procedure delivered by the Urgent PC.

Surgical. Direct sacral nerve stimulation devices consist of a surgically implanted lead near the spine and an implanted stimulator in the buttocks to deliver mild electrical pulses to the sacral nerve plexus. We believe most office-based physicians will first recommend drug therapy or PTNS treatments to patients before the more invasive, surgically implanted procedure. We believe patients may be more inclined to elect a less invasive treatment option for urinary symptoms instead of an invasive surgery that could be associated with complications.

Minimally Invasive. PTNS delivers stimulation to the sacral nerve plexus by temporarily applying electrical pulses to the posterior tibial nerve, accessed through a non-surgical, percutaneous approach on the lower leg. Neuromodulation using PTNS has a therapeutic effect documented in published clinical studies. PTNS has a low risk of complications and is typically performed in a physician's office, quite often by a physician's assistant, because it is a non-surgical treatment.

Uroplasty Solution

Urgent PC Neuromodulation System

The Urgent PC Neuromodulation System is a minimally invasive nerve stimulation device designed for office-based treatment of OAB and the associated symptoms of urge incontinence, urinary urgency and urinary frequency. Using a small-gauge needle electrode inserted above the ankle, the Urgent PC System delivers electrical impulses to the tibial nerve that travel to the sacral nerve plexus, a control center for pelvic floor and bladder function.

We believe that the Urgent PC System is the only FDA-cleared PTNS device in the United States market for treatment of OAB. Components of the Urgent PC Neuromodulation System include a hair-width needle electrode, a lead set and an external, handheld, battery-powered stimulator. For each 30-minute office-based therapy session, the physician or other qualified health care provider inserts the needle electrode above the ankle and connects the electrode to the stimulator. Typically, a patient undergoes a course of 12 consecutive weekly treatments, and, as needed, a personal treatment plan with follow-up single treatments at lesser frequency to sustain the therapeutic effect.

In late 2005, we received regulatory clearances for sale of the Urgent PC System in the United States, Canada and Europe. Subsequently, we launched the System for sale in those markets. We launched our second generation Urgent PC System in late 2006.

Urinary Incontinence

Causes of Urinary Incontinence

The mechanisms of urinary continence are complex and involve the interaction among several anatomical structures. In females, urinary continence is controlled by the sphincter muscle and pelvic floor support structures that maintain proper urethral position. The sphincter muscle surrounds the urethra and provides constrictive pressure to prevent urine from flowing out of the bladder, especially with increased intra-abdominal pressure. Urination occurs when the sphincter relaxes as the bladder contracts, allowing urine to flow through the urethra. Incontinence may result when any part of the urinary tract fails to function as intended. Incontinence may be caused by damage during childbirth, pelvic trauma, spinal cord injuries, neurological diseases (e.g., multiple sclerosis and poliomyelitis), birth defects (e.g., spina bifida) and degenerative changes associated with aging.

Table of Contents

Types of Urinary Incontinence

There are four types of urinary incontinence:

Stress Urinary Incontinence — Stress urinary incontinence (SUI), refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from ordinary physical activities, such as coughing, sneezing, laughing, straining or lifting. SUI, the most common form of urinary incontinence among women, is estimated to affect almost 30 million women over the age of 18 in the U.S. (Hampel et al., 1997 and 2000 U.S. census data). SUI is caused by urethral hypermobility and/or intrinsic sphincter deficiency (ISD). Urethral hypermobility – abnormal movement of the bladder neck and urethra – occurs when the anatomic supports for the bladder neck and urethra have weakened. This anatomical change is often the result of pregnancy or childbirth. SUI can also be caused by ISD, or the inability of the sphincter valve or muscle to function properly. ISD can be due to congenital sphincter weakness or can result from deterioration of the urethral muscular wall due to aging or damage following trauma, spinal cord lesion or radiation therapy.

Urge Incontinence — Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate. Urge incontinence often occurs when neurologic problems cause the bladder to contract and empty with little or no warning, and is part of the overactive bladder syndrome.

Overflow Incontinence — Overflow incontinence is associated with an over-distention of the bladder. This can be the result of an under-active bladder or an obstruction in the bladder or urethra.

Mixed Incontinence — Mixed incontinence is the combination of both urge and stress incontinence (and, in some cases, overflow). Since prostate enlargement often obstructs the urethra, older men often have urge incontinence coupled with overflow incontinence.

There are two general approaches to dealing with urinary incontinence. One approach is to manage symptoms, such as through absorbent products, catheters, behavior modification and drug therapy. The other approach is to undergo curative treatments in an attempt to restore continence, such as injection of urethral bulking agents or surgery, or a combination of the two. We believe that patients prefer less invasive treatments that provide the most benefit and have little or no side effects.

Treatment

Injectable Bulking Agents. Urethral bulking agents (UBAs) are injected into the area around the urethra, to augment the surrounding tissue for increased capacity to control the release of urine for patients with SUI. Hence, these materials are often called “bulking agents” or “injectables” and are an attractive alternative to surgery because they are considerably less invasive, offer a quick recovery, and do not require the use of an operating room for placement; UBAs can be implanted in an office or out-patient facility. Additionally, the use of a UBA does not preclude the subsequent use of more invasive treatments if required. Furthermore, UBAs may be used to resolve lingering symptoms for patients who have undergone certain more invasive treatments, such as mid-urethral slings, which failed to completely resolve the stress urinary incontinence conditions.

Surgery. In women, SUI may be corrected through surgery with a mid-urethral sling which provides a hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine.

Uroplasty Solution

Macroplastique

Macroplastique is used to treat adult female stress urinary incontinence due to ISD. It is designed to restore the patient's urinary continence immediately following treatment. Macroplastique is a soft-textured, permanent implant injected, under endoscopic visualization, around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone elastomer) implants suspended in a biocompatible excretable carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

We have sold Macroplastique for several urological indications in over 40 countries outside the United States since 1991. In October 2006, we received FDA pre-market approval for the use of Macroplastique to treat adult female SUI due to ISD. We began marketing Macroplastique in the United States in early 2007.

Table of Contents

Other Uroplasty Products

We also market outside of the U.S. minimally invasive products to address fecal incontinence (sometimes referred to as bowel incontinence). Our PTQ® Implants offer minimally-invasive, soft-textured permanent implant for treatment of fecal incontinence. PTQ is implanted circumferentially into the submucosa of the anal canal, creating a "bulking" and supportive effect around the anal sphincter. PTQ is CE marked and currently sold outside the United States in various international markets. The Urgent PC Neuromodulation System is also CE marked and sold outside of the United States for the treatment of fecal incontinence.

In addition to urological applications, we market our proprietary tissue bulking material outside the United States for otolaryngology vocal cord rehabilitation applications under the trade name VOX® Implants.

In The Netherlands and United Kingdom only, we distribute certain wound care products in accordance with a distributor agreement. Under the terms of the distributor agreement, we are not obligated to purchase any minimum level of wound care products.

Uroplasty Strategy

Our goal is to become the leading provider of minimally invasive, office- and outpatient surgical-based solutions to treat and improve the quality of life for patients suffering the physical and emotional stress resulting from voiding dysfunction problems. We believe that with our Urgent PC Neuromodulation System and Macroplastique products we can increasingly garner the attention of key physicians and distributors to grow our revenue. The key elements of our strategy are to:

Increase market coverage in the United States. We believe the United States presents a significant opportunity for growth in sales of our products. In order to grow our business in the United States, we anticipate further increasing our sales and marketing organization, as needed, to support our sales growth.

Educate physicians and third-party insurance carriers about the benefits of Urgent PC. We believe education of physicians and third-party insurance carriers regarding the benefits of the Urgent PC System is critical to the successful adoption of this System, and to reimbursement for treatments by third-party carriers. To this end, we have conducted clinical studies which we believe will help us with our sales and marketing efforts.

Build patient awareness of office- and outpatient surgical-based solutions. Patients often weigh the quality of life benefits of electing to undergo a surgical procedure against the invasiveness of the procedure. We intend to continue to expand our marketing efforts to build patient awareness of the treatment alternatives and encourage patients to see physicians. These marketing efforts may include patient-oriented marketing materials for physicians to use to inform patients of the availability and potential benefits of our products. Increasing patient awareness of our treatment alternatives will help physicians build their practices and simultaneously increase sales of our products.

Focus on office- and outpatient surgical-based solutions for physicians. We believe our company is uniquely positioned to provide a broad product offering of office- and outpatient surgical-based solutions for physicians. By expanding our United States presence, we intend to develop long-standing relationships with leading physicians treating voiding dysfunctions. These relationships will provide us with a source of new product ideas and a conduit through which to introduce new products. We also intend to develop marketing programs to assist physicians in marketing their practices and to provide innovative programs focused on helping physicians attract patients and develop referral networks. Building these relationships is an important part of our growth strategy, particularly for the development and introduction of new products.

Obtain FDA clearance to expand use of our Urgent PC System for other indications. Our Urgent PC Neuromodulation System is CE marked and sold outside of the United States for the treatment of fecal incontinence. We intend to explore the commercialization in the U.S of the Urgent PC System for the treatment of fecal incontinence. To commercialize the product in the U.S. for the treatment of fecal incontinence, we will need to conduct clinical trials for FDA clearance and for seeking reimbursement coverage from third-party payers. Prior to conducting a pivotal clinical study needed for FDA clearance, our plans are to undertake in fiscal 2013 a multiyear pilot clinical trial.

Develop, license or acquire new products. We believe that our office- and outpatient surgical-based solutions are an important competitive advantage because they allow us to address the preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. An important part of our long term growth strategy is to broaden our product lines further to meet customer needs by developing, licensing and acquiring new products.

Table of Contents

In fiscal 2013 we plan to start on a multiyear clinical trial and product design and development work, based on a patent we hold, for a minimally-invasive implantable tibial nerve stimulator for treatment of OAB. Our initial plans are to seek regulatory approval and CE Mark to commercialize the product in Europe, with subsequent plans to seek regulatory approval to commercialize the product in the U.S.

Sales, Distribution and Marketing

We are focusing our sales and marketing efforts primarily on urologists, urogynecologists and gynecologists with significant office-based and outpatient surgery-based patient volume.

To support our business in the United States, we have a sales organization, consisting primarily of direct field sales personnel, and a marketing organization to market our products directly to our customers and a reimbursement department. We anticipate further increasing our sales and marketing organization in the United States, as needed, to support our sales growth.

Outside of the United States, we sell our products primarily through a direct sales organization in the United Kingdom and The Netherlands, and in all other markets primarily through distributors. Each of our distributors has a territory-specific distribution agreement, including requirements indicating they may not sell products that compete directly with ours. Collectively, distributors accounted for approximately 17%, 25% and 28% of our total net sales for fiscal 2012, 2011 and 2010, respectively.

We use clinical studies and worldwide scientific community awareness programs to demonstrate the safety and efficacy of our products. This data is important to obtain regulatory approval and to support our sales staff and distributors in securing product reimbursement in their territories. Publications of clinical data in peer-reviewed journals and presentations at professional society meetings by clinical researchers add to the scientific community awareness of our products, including patient indications, treatment technique and expected outcomes. We provide a range of activities designed to support physicians in their clinical research.

Third-Party Reimbursement

In the United States as well as in foreign countries, sales of our products depend in significant part on the availability of reimbursement from third-party payers. In the United States, third-party payers consist of government programs such as Medicare, private health insurance plans, managed care organizations and other similar programs. For any product, three factors are critical to reimbursement:

coding, which ensures uniform descriptions of procedures, diagnoses and medical products;

coverage, which is the payer’s policy describing the clinical circumstances under which it will pay for a given treatment; and

payment processes and amounts.

We believe the availability of a Category 1 CPT code for PTNS treatments has encouraged, and will continue to encourage, broader use of and reimbursement for our Urgent PC System in the U.S.

Outside of the U.S., Urgent PC treatments are reimbursed under an available reimbursement code in the Netherlands. In other countries in Europe there are no specific reimbursement codes for Urgent PC treatments and generally reimbursement is from fund-holder trusts or global hospital budgets.

We believe there are appropriate CPT codes available to describe the use of Macroplastique to treat adult female SUI due to ISD in the United States. Outside of the United States, government managed health care systems and private insurance control reimbursement for devices and procedures. Reimbursement systems in international markets vary significantly by country. In the European Union, reimbursement decision-making is neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government. Reimbursement for Macroplastique has been successful in multiple international markets where hospitals and physicians have budgets approved by fund-holder trusts or global hospital budgets.

Manufacturing and Suppliers

We subcontract the manufacturing of the Urgent PC System and its related components, and have a U.S. FDA-registered manufacturing facility in Minnetonka, Minnesota, where we manufacture all of our tissue bulking products. Our facility uses dedicated heating, cooling, ventilation and high efficiency particulate air filtration systems to provide cleanroom and other controlled working environments. Our trained technicians perform all critical manufacturing processes in qualified environments according to validated written procedures. We use qualified vendors to sterilize our products using validated methods.

Table of Contents

Our manufacturing facility and systems are periodically audited by regulatory agencies and other authorities to ensure compliance with ISO 13485 (medical device quality management systems), applicable European and Canadian medical device requirements, as well as FDA's Quality Systems Regulations. We also are subject to additional state, local, and federal government regulations applicable to the manufacture of our products. While we believe we are compliant with all applicable regulations, we cannot guarantee that we will pass each regulatory audit.

We purchase several medical grade materials and other components for use in our finished products from single source suppliers meeting our quality and other requirements. Although we believe our sources of supply could be replaced if necessary without undue disruption, it is possible that the process of qualifying new suppliers could cause an interruption in our ability to manufacture our products, which could have a negative impact on sales.

Competition

The market for voiding dysfunction products is intensely competitive. Competitors offer management and curative treatments, including neuromodulation devices, urethral injectables and urethral sling products. Indirect and future competitors include drug companies and medical device firms developing new or improved treatment methods. We believe the principal decision factors among treatment methods include physician and patient acceptance of the treatment method, cost, availability of third-party reimbursement, and marketing and sales coverage. In addition to adequately addressing the decision factors, our ability to compete in this market will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors affecting our success include our product development and innovation capabilities, clinical study results, ability to obtain required regulatory approvals, ability to protect our proprietary technology, manufacturing and marketing capabilities and ability to attract and retain skilled employees.

We believe the Urgent PC Neuromodulation System offers a minimally invasive, office-based treatment alternative to the more invasive implantable Medtronic InterStim® device. The Urgent PC System is another alternative in the continuum of care for OAB patients. Conservative therapies such as dietary restrictions, pelvic floor exercises, bladder retraining, biofeedback and drugs usually precede Urgent PC treatments. The Medtronic InterStim device, which stimulates the sacral nerve, requires surgical implantation of a lead near the patient's spine in addition to a battery powered stimulator in the buttocks. In contrast, the Urgent PC Neuromodulation System allows minimally invasive stimulation of the sacral nerve plexus in an office-based setting without any surgical intervention. Other companies may also enter the U.S. market with neuromodulation or other products for the treatment of OAB. We understand Johnson & Johnson and EM Kinetics, with their nerve stimulation systems, are conducting clinical trials to demonstrate effectiveness, and Allergan, Inc., with their Botulinum toxin A (Botox®), just completed their phase III clinical trials with plans to commercialize the product.

Our Urgent PC Neuromodulation System also competes with anticholinergic medications such as Detrol® and Toviaz® (both by Pfizer Inc.); Ditropan® (Johnson and Johnson); Enablex® (Novartis); Sanctura® (Allergan)and Vesicare® (GlaxoSmithKline). These medications treat symptoms of overactive bladder, some by preventing unwanted bladder contractions and others by tightening the bladder or urethra muscles or by relaxing bladder muscles. We believe our Urgent PC Neuromodulation System competes effectively against these drugs for many patients because these drugs often have unwanted side effects such as dry eyes, dry mouth, constipation, cognitive changes and blurred vision.

Injectable urethral bulking agents for SUI competing directly with Macroplastique in the United States include: Durasphere® manufactured by Carbon Medical Technologies and distributed by Coloplast; and Coaptite® manufactured by BioForm, Inc. and distributed by Boston Scientific. We believe Macroplastique competes favorably against these products because it will not degrade, resorb or migrate, has no special preparation or storage requirements, and is safe and effective for treating adult female stress urinary incontinence.

Outside of the United States, Deflux® (manufactured by Q-Med AB, Sweden and distributed by Salix Pharmaceuticals) and Bulkamid® (manufactured by Contura, Denmark and distributed by Johnson and Johnson) compete with Macroplastique for vesicoureteral reflux and SUI, respectively.

Many of our competitors and potential competitors have significantly greater financial, manufacturing, marketing and distribution resources and experience than us. In addition, many of our competitors offer broader product lines within the urology market, which may give these competitors the ability to negotiate exclusive, long-term supply contracts and to offer comprehensive pricing for their products. It is possible other large health care and consumer products companies may enter this industry in the future. Furthermore, smaller companies, academic institutions, governmental agencies and other public and private research organizations will continue to conduct research, seek patent protection and establish arrangements for commercializing products. These products may compete directly with any products that we may offer in the future.

Table of Contents

Government Regulation

The testing, manufacturing, promotion, marketing and distribution of our products in the United States, Europe and other parts of the world are subject to regulation by numerous governmental authorities, including the FDA, the European Union and other analogous agencies.

United States

Our products are regulated in the United States as medical devices by the FDA under the Food, Drug and Cosmetic Act, or FDC Act. Noncompliance with applicable requirements can result in, among other things:

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, or total or partial suspension of production;

denial of requests for 510(k) clearance or pre-market approval of new products;

withdrawal of existing approvals; and

criminal prosecution.

Depending on the degree of risk posed by the medical device and the extent of controls needed to ensure safety and effectiveness, there are two pathways for FDA marketing clearance of medical devices. For devices deemed by FDA to pose relatively less risk (Class I or Class II devices), manufacturers, in most instances, must submit a pre-market notification requesting permission for commercial distribution, known as 510(k) clearance. Devices deemed by FDA to pose the greatest risk (Class III devices), such as life-sustaining, life-supporting or implantable devices, or a device deemed not to be substantially equivalent to a previously cleared 510(k) device, require the submission of a pre-market approval (PMA) application. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

In October 2005, our initial version of the Urgent PC System received 510(k) clearance for sale within the United States. In July 2006, our second generation Urgent PC System received 510(k) clearance for sale within the United States.

In October 2006, we received FDA pre-market approval for the use of Macroplastique to treat female stress urinary incontinence in the United States. As part of the FDA-approval process, we are conducting a customary post-market study.

After a device is placed on the market, numerous regulatory requirements apply. These include:

Quality System Regulations, which require manufacturers to follow design, testing, control, documentation and other quality assurance procedures during the manufacturing process;

labeling regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved or “off-label” uses and impose other restrictions on labeling and promotional activities;

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

notices of correction or removal, and recall regulations.

The FDC Act requires that medical devices be manufactured in accordance with FDA's current Quality System Regulations, which require, among other things, that we:

regulate our design and manufacturing processes and control them by the use of written procedures;

investigate any deficiencies in our manufacturing process or in the products we produce;

keep detailed records and maintain a corrective and preventative action plan; and

allow FDA to inspect our manufacturing facilities on a periodic basis to monitor our compliance with Quality System Regulations.

Our manufacturing facility and processes have been inspected and certified in compliance with ISO 13485, applicable European medical device directives and Canadian Medical Device Requirements.

Table of Contents

European Union and Other Regions

The European Union has adopted rules that require that medical products receive the right to affix the CE mark, which stands for Conformité Européenne. The CE mark demonstrates adherence to quality standards and compliance with relevant European medical device directives. Products that bear the CE mark can be imported to, sold or distributed within, the European Union.

Our initial version of the Urgent PC System received CE marking in November 2005. Our second generation Urgent PC System received CE mark approval and approval from the Canadian Therapeutic Products Directorate of Health in June 2006.

We received the CE mark approval for Macroplastique in 1996 for the treatment of male and female stress urinary incontinence and vesicoureteral reflux; for VOX in 2000 for vocal cord rehabilitation and; for PTQ in 2002 for the treatment of fecal incontinence. Our manufacturing facilities and processes have been inspected and certified by AMTAC Certification Services, a recognized Notified Body, a testing and certification firm based in the United Kingdom.

We currently sell our products in approximately 40 foreign countries, including those within the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We have obtained regulatory approvals in countries where required of us to sell our products. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase.

Patents, Trademarks and Licenses

We seek to establish and protect our proprietary technology using a combination of patents, trademarks, copyrights, trade secrets, and nondisclosure and non-competition agreements. We file patent applications for patentable technologies we consider important to the development of our business based on an analysis of the cost of obtaining a patent, the likely scope of protection, and the relative benefits of patent protection compared to trade secret protection, among other considerations.

We have obtained, by filing and by acquisition, various issued U.S. and foreign patents and pending patent applications related to electro-nerve stimulation. In addition, we hold multiple U.S. and foreign patents covering soft-tissue bulking materials, processes and applications. While we believe that our patents adequately protect our technologies, there can be no assurance that any of our issued patents are of sufficient scope or strength to provide meaningful protection and that any of our pending patent applications will result in patents being issued to us. In addition, there can be no assurance that any of our current or future patents will not be challenged, narrowed, invalidated or circumvented by others, or that our patents will provide us with any competitive advantage. Any legal proceedings to maintain, defend or enforce our patent rights could be lengthy and costly, with no guarantee of success. Third parties could also hold patents that may require us to negotiate licenses to conduct our business, and there can be no assurance that the required licenses would be available on reasonable terms, or at all.

We also seek to protect our trade secrets by requiring employees, consultants, and other parties to sign confidentiality agreements and noncompetition agreements, and by limiting access by outside parties to confidential information. There can be no assurance that these measures will prevent the unauthorized disclosure or use of this information or that others will not be able to independently develop this information.

In the U.S. and throughout the European Union, we have registered “Uroplasty” as our Company name, “Urgent” for our neuromodulation product, “Macroplastique” for our urological tissue bulking products, “VOX” for our otolaryngology tissue bulking products, and “PTQ” for our colorectal tissue bulking products.

We have certain royalty agreements under which we pay royalties on sales of Macroplastique and the Macroplastique implantation needle-positioning device.

Research and Development

We have a research and development program to develop, enhance and evaluate potential new incontinence products for which we incur costs for regulatory submissions, regulatory compliance and clinical research. Our expenditures for clinical research include studies for new applications or indications for existing products, post-approval regulatory compliance and marketing and reimbursement approval by third-party payers. Our expenditures for research and development totaled approximately $1.9 million, $1.7 million and $1.8 million for fiscal 2012, 2011 and 2010, respectively.

Table of Contents

Product Liability

The medical device industry is subject to substantial litigation. We face an inherent risk of liability for claims alleging adverse effects to the patient. We currently carry $10 million of worldwide product liability insurance. However, we cannot assure you that our existing insurance coverage limits are adequate to protect us from liabilities we might incur. Product liability insurance is expensive and in the future may not be available to us on acceptable terms, or at all. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any product recall. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products and our ability to generate revenues.

Compliance with Environmental Laws

Compliance by us with applicable environmental requirements during fiscal years 2011 and 2010 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During fiscal 2012, 2011 and 2010, none of our customers accounted for 10% or more of our net sales.

Backlog

We did not have significant backlog at fiscal year end 2012, 2011 or 2010. We process customer orders generally within one or two days of receipt of the order.

Employees

As of March 31, 2012, we had 108 employees, of which 104 were full-time and 4 were part-time. No employee was subject to a collective bargaining agreement. We believe we maintain good relations with our employees.

Incorporation and Current Subsidiaries

We were incorporated in January 1992 as a Minnesota corporation and a wholly owned subsidiary of our original parent. In February 1995, we became a stand-alone, privately held company pursuant to a Plan of Reorganization confirmed by the U.S. Bankruptcy Court. We became a reporting company pursuant to a registration statement filed with the Securities and Exchange Commission in July 1996.

Our wholly owned foreign subsidiaries and their respective principal functions are as follows:

Uroplasty BV	Incorporated in The Netherlands, distributes the Urgent PC Neuromodulation System, Macroplastique Implants, VOX Implants, PTQ Implants, all of their accessories, and wound care products. Products are sold primarily through distributors.
Uroplasty LTD	Incorporated in the United Kingdom and acts as the sole distributor of the Urgent PC Neuromodulation System , Macroplastique Implants, PTQ Implants, all of their accessories, and wound care products in the United Kingdom and Ireland. Products are sold primarily through a direct sales organization.

Item 1A. Risk Factors

Our operations are subject to a number of risks and uncertainties that may affect our financial results, our accounting, and the accuracy of the statements we make in this Form 10-K. For example, we make statements about our belief in the efficacy of our product, the impact of regulatory and reimbursement approvals on our products and revenues, trends in international regulation, the attributes of our products versus those of our competitors, the adequacy of our resources, including cash, available to us, and other matters all of which represent our expectations or beliefs about future events. Our actual results may vary from these expectations because of a number of factors that affect our business, the most important of which include the following:

Table of Contents

We continue to incur losses and may never reach profitability

We have incurred net losses in each of the last five fiscal years. As of March 31, 2012, we had an accumulated deficit of approximately $36 million primarily because of costs relating to the development, including seeking regulatory approvals, and commercialization of our products. We expect our operating expenses relating to sales and marketing activities, product development and clinical trials, including an FDA-mandated post-market clinical study for our Macroplastique product, will continue during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability to achieve widespread market acceptance and third-party reimbursement for our products and successfully expand our business in the U.S. We may never achieve substantial market acceptance, realize significant revenue from the sale of our products or be profitable.

The use and acceptance of our products is heavily dependent upon the availability of third-party reimbursement for the procedures in which our products are used.

In the United States, healthcare providers that purchase medical devices, including our products, generally rely on third-party payers, including Medicare, Medicaid, private health insurance carriers and managed care organizations, to reimburse all or part of the cost and fees associated with the procedures performed using these devices. The commercial success of our products will depend on the ability of healthcare providers to obtain adequate reimbursement from third-party payers for the procedures in which our products are used. Third-party payers are increasingly challenging the coverage and pricing of medical products and procedures.

Even if a procedure is eligible for reimbursement, the level of reimbursement may not be adequate to justify the use of our products. In addition, third-party payers may deny reimbursement if they determine that the device used in the treatment was not cost-effective or was used for a non-approved indication, particularly if there is not a published CPT code for reimbursement. For example, in 2009, the AMA advised the medical community that the previously recommended Category 1 CPT code for PTNS treatments should be replaced with an unlisted code. As a result, many third-party insurers delayed or denied reimbursement for PTNS treatments, significantly impacting the sales of our Urgent PC, until a new code was effective in January 2011.

The availability of the new Category 1 CPT code for PTNS treatments has encouraged broader use of our Urgent PC Neuromodulation System, but it has not resulted in universal coverage and there can be no assurance that additional payers will agree to create coverage policies or that the policies, if they create, will provide adequate reimbursement, that existing coverage will not again be challenged (as it was in fiscal 2009), or that government actions will not decrease the level of reimbursement.

Reimbursement and healthcare payment systems in international markets vary significantly by country, with some countries offering government-sponsored healthcare or private insurance, or both. In many countries where there is government-sponsored healthcare reimbursement, decisions are made by individual hospitals with the government setting an upper limit of reimbursement. In most foreign countries, there are also insurance systems that may offer payments for alternative procedures. We cannot be certain that we, or in countries in which we work with our distributors, will successfully and cost-effectively manage all of these payment systems.

All third-party reimbursement programs, whether government-funded or insured commercially, inside the United States or outside, are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These types of programs can potentially limit the amount that healthcare providers may be willing to pay for medical devices and could have a material adverse effect on our financial position and results of operations.

Medicare claims administrators are scheduled to undergo consolidation and reimbursement could be affected by this consolidation.

The Centers for Medicare and Medicaid Services expects to consolidate the Medicare claims regions over the next several years, and to correspondingly reduce or consolidate claims administrators. To the extent that, as part of this consolidation, regions in which there is coverage for PTNS treatments are consolidated into a region that does not provide coverage for PTNS treatments, it is unclear whether PTNS treatments using our Urgent PC will continue to be reimbursed, or, if reimbursed, whether the coverage will remain unchanged. Some of the future consolidation decisions have been announced and are currently being disputed by administrators whose regions were reduced or eliminated, creating uncertainty in the marketplace. Accordingly, this consolidation process and the uncertainty it creates could negatively impact reimbursement for PTNS treatments using our products, and negatively impact our sales.

Table of Contents

We cannot predict how quickly or how broadly the market will accept our products.

In addition to the availability of third-party reimbursement, market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefits, and cost-effectiveness of our products compared to products or treatment options of our competitors. We cannot assure you that we will be successful in educating the marketplace about the benefits of our products. Our Urgent PC product requires a new treatment protocol for the physicians and their staff to implement repeatedly. Even if customers accept our products, this acceptance may not translate into repeat sales if our customers do not fully adopt the new treatment protocol in their practice.

We may be subject to changing federal regulation that increases the cost of doing business or imposes requirements with which we cannot comply

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators and third-party payers to control these costs and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products and could limit the acceptance and availability of our products. Moreover, as discussed below, recent federal legislation will impose significant new taxes on medical device makers such as us. The adoption of some or all of these proposals, including the recent federal legislation, could have a material adverse effect on our financial position and results of operations.

On March 23, 2010, President Obama signed the Patient Protection and Affordable Care Act. The legislation imposes significant new taxes on medical device makers. Under the legislation, the total cost to the medical device industry would be approximately $20 billion over ten years. These taxes will result in a significant increase in the tax burden on our industry, which could have a material, negative impact on our results of operations and our cash flows. Other elements of this legislation such as comparative effectiveness research, an independent payment advisory board, payment system reforms, including shared savings pilots, and other provisions could meaningfully change the way healthcare is developed and delivered, and may materially impact numerous aspects of our business.

Further, the FDA has recently significantly increased the scrutiny applied to 510(k) submissions, and it may also focus more scrutiny on other regulation within its purview. Both the FDA and the United States Congress are influenced by high profile events, injuries and cases that generate publicity and public attention, and new legislation is often generated as a result of those events. There can be no assurance that new products we introduce will not be delayed by the current level of scrutiny applied to applications at the FDA or that new laws and regulations will not be adopted that impact the cost of production and marketing of our existing products.

If we are not able to attract, retain and motivate our sales force and expand our distribution channels, our sales and revenues will suffer.

In the U.S., we have a sales organization consisting primarily of direct sales representatives, and a marketing organization to market our products directly and support our distributor organizations. We expect to expand our sales and marketing organization, as needed to support our growth. We have and will continue to incur significant continued additional expenses to support this organization. We cannot be certain that our sales organization will be able to generate sales of Urgent PC at levels that justify its expense, or even if it can, that we will be able to recruit, train, motivate or retain qualified sales and marketing personnel or independent sales representatives. Outside of the United States, United Kingdom and The Netherlands, we sell our products through a network of independent distributors. Our ability to increase product sales in foreign markets will largely depend on our ability to develop and maintain relationships with our distributors and on their ability to successfully market and sell our products. We may not be able to retain distributors who are willing to commit the necessary resources to market and sell our products to the level of our expectations. Failure to maintain or expand our distribution channels or to recruit, retain and motivate

qualified personnel could have a material adverse effect on our product sales and revenues.

The size and resources of our competitors may render it difficult for us to successfully compete in the marketplace.

Our products compete against similar medical devices and other treatment methods, including drugs, for treating voiding dysfunctions. Many of our competitors, which include some of the largest medical products and pharmaceutical companies in the world, have significantly greater financial, research and development, manufacturing and marketing resources than we have. Our competitors could use these resources to develop or acquire products that are safer, more effective, less invasive, less expensive or more readily accepted than our products. Their products could make our technology and products obsolete or noncompetitive. Our competitors could also devote greater resources to the marketing and sale of their products and adopt more aggressive pricing policies than we can.

Table of Contents

We are primarily dependent on sales of two product lines and our business would suffer if sales of either of these product lines decline.

Currently, we are dependent on sales of our Urgent PC System and Macroplastique products. In fiscal 2012, sales of our Urgent PC System and Macroplastique accounted for approximately 48% and 49%, respectively, of our total revenue. If demand for any or both of the product lines declines, our revenues and business prospects may suffer.

We may require additional financing and may find it difficult to obtain the financing on favorable terms, or at all.

Our future liquidity and capital requirements will depend on numerous factors, including: the timing and cost required to expand our sales, marketing and distribution capabilities in the United States markets; the cost and effectiveness of our marketing and sales efforts of our products in international markets; the effect of competing technologies and market, reimbursement and regulatory developments; and the cost involved in protecting our proprietary rights. Although we currently have an adequate cash balance, we may need to raise additional financing to support our operations and planned growth activities in the future because we have yet to achieve profitability and generate positive cash flows. Any equity financing could substantially dilute your equity interests in our company and any debt financing could impose significant financial and operational restrictions on us. We cannot assure you that we will obtain additional financing on acceptable terms, or at all.

We could be subject to fines and penalties, or required to temporarily or permanently cease offering products, if we fail to comply with the extensive regulations applicable to the sale and manufacture of medical products.

The production and marketing of our products and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the testing, marketing and pre-market review of new medical devices, and the manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain regulatory approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot assure you that the regulatory authority we currently possess to market our products will remain available, or that we will be able to obtain authority to sell new or existing products in new markets. Further the manufacture and manufacturing facilities of medical products are subject to periodic reviews and inspection by the FDA and foreign regulatory authorities. Our failure to comply with regulatory requirements could result in governmental agencies:

imposing fines and penalties on us;

preventing us from manufacturing or selling our products;

bringing civil or criminal charges against us;

delaying the introduction of our new products into the market;

enforcing operating restrictions on us;

recalling or seizing our products; or

withdrawing or denying approvals or clearances for our products.

Even if we receive regulatory approval or clearance of a product, the approval or clearance could limit the uses for which we may label and promote the product, which may limit the market for our products.

Our distributors may not obtain regulatory approvals in a timely basis, or at all.

We may rely on our distributors in countries outside the United States in seeking regulatory approval to market our products in particular countries. To the extent we do so, we are dependent on persons outside of our direct control to make regulatory submissions and secure approvals, and we do or will not have direct access to health care agencies in those markets to ensure timely regulatory approvals or prompt resolution of regulatory or compliance matters. If our distributors fail to obtain the required approvals or do not do so in a timely manner, our sales from our international operations and our results of operations may be adversely affected.

We may not have the resources to successfully market our products, which would adversely affect our business and results of operations.

The marketing of our products requires a significant amount of time and expense in order to identify the physicians who would use our products and to train a sales force that is large enough to interact with the targeted physicians. The ease and predictability of third-party reimbursement significantly impacts the success of our marketing activities. We may not have adequate resources to market our products successfully against larger competitors who have more resources than we do. If we cannot market our products successfully, our business and results of operations would be adversely affected.

Table of Contents

If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected product.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties' intellectual property rights. Our efforts to identify and avoid infringing on third parties' intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

be expensive and time consuming for us to defend;

result in us being required to pay significant damages to third parties;

cause us to cease making or selling products that incorporate the challenged intellectual property;

require us to redesign, reengineer or rebrand our products, if feasible;

require us to enter into royalty or licensing agreements in order to obtain the right to use a third party's intellectual property, which agreements may not be available on terms acceptable to us, or at all;

divert the attention of our management; or

result in our customers or potential customers deferring or limiting their purchases or use of the affected products until resolution of the litigation.

In addition, new patents obtained by our competitors could threaten our product's continued life in the market even after it has already been introduced.

If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively.

Our success depends in part on our ability to protect the proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep a competitive advantage. Our patents and patent applications if issued may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us.

We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent products or processes or otherwise gain access to our unpatented proprietary technology. We attempt to protect our trade secrets and other unpatented proprietary technology through the use of confidentiality and noncompetition agreements with our current key employees and with other parties to whom we have divulged trade secrets. However, these agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event competitors discover or

independently develop similar proprietary information.

Efforts on our part to enforce any of our proprietary rights could be time-consuming and expensive, which could adversely affect our business and prospects and divert our management's attention.

Product liability claims could adversely affect our business and results of operations.

The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Any defects or risks that we have not yet identified with our products may give rise to product liability claims. Our existing $10 million of worldwide product liability insurance coverage may be inadequate to protect us from liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer. Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. A recall of any of our products likely would be costly, would be uninsured and could also result in increased product liability claims. Further, while we train our physician customers in the proper use of our products, we cannot be certain that they will implement our instructions accurately. If our products are used incorrectly by our customers, injury may result and this could give rise to product liability claims against us.

Table of Contents

The loss or interruption of materials from any of our key suppliers could delay the manufacture of our products, which would limit our ability to generate sales and revenues.

We currently purchase several key materials used in our products from single source suppliers, including the finished products for our Urgent PC System. If one of these suppliers delayed or curtailed shipments to us, our ability to manufacture and deliver product would be impaired, our sales would decline or be curtailed for that product, and we would be forced to quickly locate an alternative source of supply. We cannot be sure that acceptable alternative arrangements could be made on a timely basis. Further, our reliance on such suppliers and the cost and difficulty we would encounter in qualifying an alternative subjects us to increased risk of price increase by single source suppliers. Additionally, the qualification of materials and processes as a result of a supplier change could be deemed as unacceptable to regulatory authorities and cause delays and increased costs due to additional test requirements. A significant interruption in the supply of materials, for any reason, could delay the manufacture and sale of our products, which would limit our ability to generate revenues.

If we are not able to maintain sufficient quality controls, regulatory approvals of our products by the European Union, Canada, the FDA or other relevant authorities could be delayed or denied and our sales and revenues will suffer.

The FDA, European Union, Canada or other related authorities could stop or delay approval of production of products if our manufacturing facilities do not comply with applicable manufacturing requirements. The FDA's Quality System Regulations impose extensive testing, control, documentation and other quality assurance requirements. Canada and the European Union also impose requirements on quality systems of manufacturers, who are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Further, our suppliers are also subject to these regulatory requirements. Failure by any of our suppliers or us to comply with these requirements could prevent us from obtaining or retaining approval for and marketing of our products.

If we are not able to acquire or license other products, our business and future growth prospects could suffer.

As part of our growth strategy, we intend to acquire or license additional products and technologies for development and commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right products and technologies.

Products and technologies that we license or acquire may require additional development prior to sale, including clinical testing and approval by the FDA and other regulatory bodies, and we may encounter difficulty or delays in completing the development or receiving the necessary approvals. We may find that the product or technology cannot be manufactured economically or commercialized successfully. We may not be able to acquire or license the right to products on terms that we find acceptable, or at all.

Even if we complete future acquisitions, our business, financial condition and the results of operations could be negatively affected because:

- we may be unable to integrate the acquired business or products successfully and realize anticipated economic, operational and other benefits in a timely manner; and
- the acquisition may disrupt our ongoing business, distract our management and divert our resources.

Our business strategy relies on assumptions about the market for our products, which, if incorrect, would adversely affect our business prospects and profitability.

We are focused on the market for minimally invasive therapies used to treat voiding dysfunctions. We believe that the aging of the general population will continue and that these trends will increase the need for our products. However, the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize. Actual demand for our products could also be affected if drug therapies gain more widespread acceptance as a viable alternative treatment, which in each case would adversely affect our business prospects and profitability.

Table of Contents

Negative publicity regarding the use of silicone material in medical devices could harm our business and result in a material decrease in revenues.

Macroplastique is comprised of medical grade, heat-vulcanized polydimethylsiloxane, which results in a solid, flexible, highly-textured silicone elastomer. In the early 1990's, the United States silicone gel breast implant industry became the subject of significant controversies surrounding the possible effects upon the human body of the use of semi-liquid silicone gel in breast implants, resulting in product liability litigation and leading to the bankruptcy of several companies. We use only medical grade solid silicone material in our tissue bulking products and do not use semi-liquid silicone gel, as was used in breast implants. Negative publicity regarding the use of silicone materials in our products or in other medical devices could have a significant adverse affect on the overall acceptance of our products.

We derive a significant portion of our sales from outside of the United States and are subject to the risks of international operations.

We derived approximately 33% of our sales in fiscal 2012 from customers and operations in international markets and expect such sales to continue to represent a significant portion of our revenues. The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to a number of risks, including:

the imposition of additional U.S. and foreign governmental controls or regulations;

the imposition of costly and lengthy export licensing requirements;

local political and economic instability;

fluctuations in the value of the U.S. dollar relative to foreign currencies;

difficulties in recruiting and maintaining distributors and staff in remote locations, including sales people;

changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

the imposition of new trade restrictions;

the imposition of restrictions on the activities of foreign agents, representatives and distributors;

foreign taxation compliance and penalties;

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; and

difficulties in enforcing or defending intellectual property rights.

We cannot assure you that one or more of these factors will not harm our business.

If we lose the services of our chief executive officer or other key personnel, we may not be able to manage our operations and meet our strategic objectives.

Our success depends, in large part, on the continued service of our senior management. We have no key person insurance with respect to any of our senior managers, and any loss or interruption of their services could significantly reduce our ability to effectively manage our operations and implement our strategy.

Our stock is thinly traded and you may find it difficult to sell your investment in our stock at quoted prices.

There is only a limited trading market for our common stock, which is quoted on the NASDAQ. Transactions in our common stock may lack the volume, liquidity and orderliness necessary to maintain a liquid and active trading market and relatively small purchases or sales orders may have significant swings on trading prices.

Our stock price may fluctuate and be volatile.

The market price of our common stock may be subject to significant fluctuations due to the following factors, among others:

variations in our quarterly financial results;

Table of Contents

developments regarding regulatory clearances or approvals of our products;

market acceptance of our products;

the success of our efforts to acquire or license additional products;

announcements of new products or technologies by us or our competitors;

developments regarding our patents and proprietary rights or those of our competitors;

developments in U.S. or international reimbursement systems;

changes in accounting standards, policies, guidance or interpretations;

sales of substantial amounts of our stock by existing shareholders; and

general economic conditions, including the current economic downturn.

The stock market in recent years has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. These broad market fluctuations may cause the price of our common stock to fall abruptly or remain significantly depressed.

Future sales of our common stock in the public market could lower our share price.

The market price of our common stock could decline due to sales by our existing shareholders of a large number of shares of our common stock or the perception that these sales could occur. These sales could also make it more difficult for us to raise capital through the sale of common stock at a time and price we deem appropriate.

We have a significant number of equity instruments outstanding subject to conversion to our common stock. As of March 31, 2012, we have 2.1 million shares of our common stock subject to outstanding options.

Our corporate documents and Minnesota law contain provisions that could discourage, delay or prevent a change in control of our company.

Provisions in our articles of incorporation may discourage, delay or prevent a merger or acquisition, even if our stockholders consider the terms favorable. Our articles of incorporation provide for a staggered board of directors, requiring our directors to serve for three-year terms, with approximately one third of the directors standing for reelection each year. A staggered board could make it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

We are also subject to the anti-takeover provisions of Section 302A.673 of the Minnesota Business Corporation Act. Under these provisions, if anyone becomes an “interested shareholder” in a transaction not approved by a committee consisting of disinterested members of our board of directors, we may not enter into a “business combination” with that person for four years, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 302A.673, “interested shareholder” generally means someone owning 10% or more of our outstanding voting stock or an affiliate of ours that owned 10% or more of our outstanding voting stock during the past four years, subject to certain exceptions.

We do not intend to declare dividends on our stock in the foreseeable future.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all future earnings, if any, for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on our common stock will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, financial condition, future prospects, contractual restrictions and other factors deemed relevant by our board of directors. Therefore, you should not expect to receive dividend income from shares of our common stock.

Item 2. Description of Property

We lease an 18,259 square-foot office, warehouse and manufacturing facility in Minnetonka, Minnesota for our corporate headquarters pursuant to a lease expiring in 2014. We also own 9,774 square feet of office and warehouse space in Geleen, The Netherlands. We believe that these facilities are adequate for our operations for the foreseeable future.

Table of Contents

Item 3. Legal Proceedings

There are no material pending legal proceedings other than ordinary routine litigation incidental to the Company's business.

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents

PART II

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

Market Information. Our common stock has been listed on the NASDAQ Capital Market under the symbol "UPI" since July 12, 2010, and was listed on the NYSE AMEX prior to that date.

The following table sets forth the high and low closing prices for our common stock for our fiscal years ended March 31, 2012 and 2011 as reported on the NYSE AMEX and, on and after July 12, 2010, the NASDAQ Capital Markets.

Fiscal year ended March 31, 2012	Low	High
First Quarter	$ 6.33	$ 8.32
Second Quarter	4.50	9.00
Third Quarter	3.87	5.85
Fourth Quarter	2.66	4.45

Fiscal year ended March 31, 2011	Low	High
First Quarter	$ 2.23	$ 6.49
Second Quarter	3.64	4.81
Third Quarter	3.66	5.81
Fourth Quarter	4.24	6.63

Fiscal year ended March 31, 2010	Low	High
First Quarter	$ 0.66	$ 1.07
Second Quarter	0.61	1.26
Third Quarter	1.03	2.03
Fourth Quarter	1.44	2.25

As of March 31, 2012, we had approximately 350 holders of record of our common stock. Registered ownership includes nominees who may hold securities on behalf of multiple beneficial owners.

Securities Authorized for Issuance Under Equity Compensation Plans. The following table provides particular information regarding our equity compensation plans as of March 31, 2012.

	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding

			Securities Reflected in the First Column)
Equity Compensation Plans Approved by Security Holders (1)	1,183,000	$ 3.33	1,141,000
Equity Compensation Plans Not Approved by Security Holders (2)	900,000	$ 4.05	-
Total	2,083,000	$ 3.64	1,141,000

(1) Consists of options outstanding under our 2006 Amended Stock and Incentive Plan.

(2) Represents non-qualified options to purchase shares of our common stock (all of which are vested), granted outside of any plan.

Table of Contents

Stock Performance Graph. The following graph compares the 5-year cumulative total shareholder return of our common stock to the NASDAQ U.S. index and to the NASDAQ Surgical and Medical Instruments and Supplies Index, assuming an initial investment of $100.

Item 6. Selected Financial Data

Summary Statement of Operations Data (in thousands except per share data)

For the fiscal year ended March 31,

	2012	2011	2010	2009	2008
Net sales	$20,562	$13,787	$11,863	$14,742	$13,856
Gross profit	17,525	11,401	9,804	12,458	10,921
Operating loss	(4,266)	(4,698)	(3,203)	(3,622)	(3,929)
Net loss	(4,250)	(4,648)	(3,204)	(3,578)	(3,824)
Basic and diluted loss per share	$(0.21)	$(0.25)	$(0.21)	$(0.24)	$(0.28)
Basic and diluted weighted average shares outstanding	20,690	18,874	14,944	14,923	13,839
Other data					
Share-based expense, and depreciation and amortization	$1,803	$1,553	$1,553	$1,885	$2,111

Summary Balance Sheet Date (in thousands)

At March 31,

	2012	2011	2010	2009	2008
Working capital	$13,081	$14,650	$6,056	$7,838	$10,579
Total assets	22,291	25,727	11,574	14,681	19,290
Shareholders' equity	19,235	22,629	9,215	12,309	15,603

Table of Contents

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

You should read this discussion of our financial condition and results of operations in conjunction with, and we qualify our discussion in its entirety by, the consolidated financial statements and notes thereto included elsewhere within this Annual Report on Form 10-K, the material contained under Part 1, Item 1. "Description of Business" and Part I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K, and the cautionary disclosure about forward-looking statements at the front of Part I of this of this Annual Report on Form 10-K.

Overview

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our primary focus is on two products: the Urgent PC® Neuromodulation System, which we believe is the only FDA-cleared minimally invasive, office-based neuromodulation therapy for the treatment of overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence; and Macroplastique® Implants a urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency (ISD). Outside of the U.S., our Urgent PC System is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence and vesicoureteral reflux.

Our sales during the past four years have been significantly influenced by the availability of third-party reimbursement for PTNS treatments. Sales of our Urgent PC System grew rapidly during fiscal 2007 and 2008 with rapid market acceptance of PTNS treatments that were reimbursed under a listed Current Procedure Technology (CPT®) code. However, during the first quarter of our fiscal 2009 the American Medical Association (AMA) advised the medical community that the previously recommended listed CPT code for reimbursement for PTNS treatments be replaced with an unlisted CPT code. As a result, many third-party insurers delayed or denied reimbursement for PTNS treatments, and sales of our Urgent PC System in the U.S. declined from a peak of $2.2 million in the first quarter of our fiscal 2009 to a range of $0.9 million to $1 million per quarter in the six subsequent fiscal quarters ended December 2010.

We responded by sponsoring several randomized, controlled clinical studies over the following two years, and supported by publication of these clinical studies in U.S. peer-reviewed journals, we applied for, and effective January 2011 the AMA granted, a Category 1 CPT code for PTNS treatments. The AMA advised us of this decision prior to the effective date and we began to expand our sales organization in anticipation of increased interest in our Urgent PC. We have expanded our U.S. field sales and support organization from 15 employed sales representatives and six independent manufacturer's representatives on April 1, 2010 to 39 employed sales representatives and one independent manufacturer's representative on March 31, 2012. Our employed sales representatives generated approximately 99% of our U.S. sales in the fourth quarter of fiscal 2012 and approximately 97% in fiscal 2012.

We also focused our efforts on expanding reimbursement coverage with the Medicare carriers and private payers by instituting a comprehensive program to educate their medical directors regarding the clinical effectiveness, cost effectiveness and patient benefits of PTNS treatments using our Urgent PC System. As of March 31, 2012, ten regional Medicare carriers representing 35 states, with approximately 31 million covered lives, provide coverage for PTNS treatments. In addition, we estimate that private payers providing insurance to approximately 84 million lives provide coverage for PTNS treatments.

With the availability of a CPT Category 1 code and expanded reimbursement coverage from third-party payers, as well as an expanded sales organization, our U.S. Urgent PC sales of $7.8 million in the year ended March 31, 2012 grew 84% over sales during the year ended March 31, 2011. In addition, because of the discontinuation in the marketplace of a competing product and our expanded sales organization, sales of our Macroplastique product in the

U.S. of $5.9 million in the year ended March 31, 2012 grew 69% over sales during the year ended March 31, 2011.

At March 31, 2012, three regional Medicare carriers representing 15 states, with approximately 17 million covered lives, continued to decline reimbursement coverage for PTNS treatments. We participated during fiscal 2012 with two Medicare beneficiaries who filed administrative appeals for reconsideration of the decisions of two of those regional Medicare carriers. In April 2012, one of those two regional Medicare carriers, with 4.6 million covered lives, retired its negative coverage decision and subsequently in May 2012 published their decision to cover PTNS treatments retroactive to April 9, 2012. The second appeal remains pending. We also understand that in calendar 2012, and as part of the plans announced by the Centers for Medicare and Medicaid Services to consolidate the regional carriers, two regional Medicare carriers currently reimbursing for PTNS treatments are expected to be consolidated into the regional Medicare carrier that recently retired its negative policy.

The Centers for Medicare and Medicaid Services expects to continue to consolidate the regional Medicare claims administrators and there is no guarantee that Medicare beneficiaries in a region with reimbursement coverage will continue to be reimbursed when consolidated into a regional Medicare carrier with a negative reimbursement policy, or, if reimbursed, the coverage would remain unchanged. We continue to work with the medical directors of both Medicare and private payers to expand coverage of PTNS treatments, and to ensure that coverage continues after the number of Medicare regions is decreased and regional Medicare administrators are transitioned.

Table of Contents

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require us to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing these consolidated financial statements, we have made our best estimates and judgments of certain amounts, giving due consideration to materiality. We believe that of our significant accounting policies, the following can be characterized as "critical accounting policies" and are particularly important to the portrayal of our results of operations and financial position. These critical policies may require the application of a higher level of judgment by us, and as a result are subject to an inherent degree of uncertainty.

Revenue Recognition. We recognize revenue when persuasive evidence of an arrangement exists, title and risk of ownership have passed, the sales price is fixed or determinable and collectability is reasonably assured. Generally, these criteria are met at the time the product is shipped to the customer. We include in net sales shipping and handling charges that we bill to customers, and include the related shipping and handling costs that we incur in cost of goods sold. We present our sales in our income statement net of taxes, such as sales, use, value-added and certain excise taxes, collected from the customers and remitted to governmental authorities. Typically our agreements contain no customer acceptance provisions or installation obligations. We sell our products to clinics, healthcare institutions, physicians and other healthcare providers, and to distributors. The distributor payment terms are not contingent on the distributor selling the product to end users. Customers do not have the right to return unsold products except for warranty claims. Our distributors purchase our products to meet the sales demand of their end-user customers as well as to fulfill their internal requirements associated with the sales process and, if applicable, contractual purchase requirements under the respective distribution agreements. Internal and other requirements include purchases of products for training, demonstration and evaluation purposes, clinical evaluations, product support, establishing inventories, and meeting minimum purchase commitments. As a result, the level of our net sales during any period is not necessarily indicative of our distributors' sales to end-user customers during that period, which we estimate are not substantially different than our sales to those distributors in each of the last three years. Our distributors' level of inventories of our products, their sales to end-user customers and their internal product requirements may impact our future revenue growth.

Accounts Receivable. We carry our accounts receivable at the original invoice amount less an estimated allowance for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts based on the customer's financial health, and both historical and expected credit loss experience. We write off our accounts receivable when we deem them uncollectible. We record recoveries of accounts receivable previously written off when received. We are not always able to accurately or timely anticipate changes in the financial condition of our customers and if circumstances related to our customers deteriorate, our estimates of the recoverability of accounts receivable could be materially affected and we may be required to record additional allowances. Alternatively, if more allowances are provided than are ultimately required, we may reverse a portion of such provisions in future periods based on the actual collection experience. Historically, the accounts receivable balances we have written off have generally been within our expectations.

Inventories. We state inventories at the lower of cost or market using the first-in, first-out method. We provide lower of cost or market reserves for slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. In assessing the ultimate realization of inventories, we make judgments as to future demand requirements compared with inventory levels. While we expect our sales to grow, a reduction in sales could reduce the demand for our products and may require additional inventory reserves. Historically, inventories we have written off have generally been within our expectations.

Foreign Currency Translation/Transactions. The financial statements of our foreign subsidiaries are translated in accordance with the provisions of Accounting Standards Codification (ASC) 830 "Foreign Currency Matters." We

translate all assets and liabilities using period-end exchange rates, and we translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders' equity. We recognize foreign currency transaction gains and losses in the statement of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates, resulting in an increase in the volatility of our consolidated statements of operations.

Impairment of Long-Lived Assets. Our long-lived assets consist of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. We measure the recoverability of assets to be held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. We use judgment to forecast future cash flows including forecasting revenues and margins, and working capital needs. If we consider such assets impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We did not record any impairment charge in fiscal years 2012, 2011 or 2010.

Table of Contents

Share-Based Compensation. We account for share-based compensation costs under ASC 718, "Compensation – Stock Compensation". ASC 718 covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. We recognize the compensation cost relating to share-based payment transactions, including grants of employee stock options and restricted shares, in our financial statements. We measure that cost based on the fair value of the equity or liability instruments issued.

Defined Benefit Pension Plans. We have a liability attributed to defined benefit pension plans we offered to certain former and current employees of our subsidiaries in the UK and the Netherlands. The liability is dependent upon numerous factors, assumptions and estimates, and the continued benefit costs we incur may be significantly affected by changes in key actuarial assumptions such as the discount rate, mortality, compensation rates, or retirement dates used to determine the projected benefit obligation. Additionally, changes made to the provisions of the plans may impact current and future benefit costs. In accordance with the provisions of ASC 715, "Compensation – Retirement Benefits", changes in benefit obligations associated with these factors may not be immediately recognized as costs in the statement of operations, but are recognized in future years over the expected average future service of the active employees or the average remaining life expectancies of inactive employees.

Income Taxes. We recognize deferred tax assets and liabilities for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. We measure deferred tax assets and liabilities using enacted tax rates we expect to apply to taxable income in the years in which we expect to recover or settle those temporary differences. As of March 31, 2012, we have generated approximately $30 million in U.S. net operating loss carryforwards that we cannot use to offset taxable income in foreign jurisdictions. We recognize a valuation allowance when we determine it is more likely than not that we will not realize a portion of the deferred tax asset. We have established a valuation allowance for U.S. and certain foreign deferred tax assets due to the uncertainty that we will generate enough income in those taxing jurisdictions to utilize the assets.

In addition, future utilization of NOL carryforwards is subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. We believe that we had an "ownership change" under Section 382 with the issuance of our common stock in public offerings in December 2006 and also in July 2010. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 and after December 2006 and prior to July 2010 are limited.

See Note 6 to our consolidated financial statements for further discussion.

Results of Operations

Net Sales. In fiscal 2012, net sales were $20.6 million, representing a $6.8 million or 49% increase compared to net sales in fiscal 2011. Excluding the translation impact of fluctuations in foreign currency exchange rates, net sales increased by approximately 47%. In fiscal 2011, net sales were $13.8 million, representing a $1.9 million or 16% increase compared to net sales in fiscal 2010. Excluding the translation impact of fluctuations in foreign currency exchange rates, net sales increased by approximately 19%. The increase in consolidated net sales over these periods is attributed primarily to the growth in U.S. sales.

In fiscal 2012, net sales to customers in the U.S. of $13.9 million, represented an increase of $5.9 million, or 75%, over net sales in fiscal 2011. In fiscal 2011, net sales to customers in the U.S. of $7.9 million, represented an increase of $1.8 million, or 31%, over net sales in fiscal 2010.

Net sales in the U.S. of our Urgent PC product increased 84% to $7.8 million in fiscal 2012, from $4.3 million in fiscal 2011. Net sales increased because of the full year impact of the new Category 1 CPT code effective January

2011 and the expanded reimbursement coverage by third-party payers, as well as the impact of our expanded direct sales organization. Net sales in the U.S. of our Urgent PC System increased 11% in fiscal 2011, from $3.8 million in fiscal 2010 reflecting one quarter's results under the new Category 1 CPT code and an upward trend in sequential quarterly growth in the number of customers and the resulting increase in the sale of the lead sets. In the fiscal first quarter ended June 30, 2011 we had 401 customers purchasing 1,985 lead set boxes. In the fiscal fourth quarter ended March 31, 2012 we had 538 customers purchasing 3,023 lead set boxes. We are expanding the customer base and the customers have ramped-up their practice in light of the decision by several Medicare carriers and private payers to cover PTNS treatments using our Urgent PC.

Table of Contents

Net sales in the U.S. of our Macroplastique product increased 69% to $5.9 million in fiscal 2012, from $3.5 million in fiscal 2011. In fiscal 2011 net sales in the U.S. of our Macroplastique product increased 60%, from $2.2 million in fiscal 2010. The increase in net sales of our Macroplastique product over these periods is a result of our increased sales and marketing focus, and in fiscal 2012 also as a result of the discontinuation in the marketplace of a competing product.

Net sales to customers outside the U.S. were $6.7 million in fiscal 2012, compared to $5.9 million in fiscal 2011, an increase of 14%. Excluding the translation impact of fluctuations in foreign currency exchange rates, net sales increased by approximately 10%. Fiscal 2012 includes $2 million of Urgent PC sales, which increased 52% from $1.3 million in fiscal 2011. Excluding the translation impact of fluctuations in foreign currency exchange rates, Urgent PC sales increased by approximately 48%. In fiscal 2011 net sales to customers outside the U.S. increased 1%, from $5.8 million in fiscal 2010. Excluding the translation impact of fluctuations in foreign currency exchange rates, net sales increased by approximately 7%.

Gross Profit: Gross profit was $17.5 million in fiscal 2012 and $11.4 million in fiscal 2011, or 85% of net sales in fiscal 2012, and 83% in fiscal 2011. The increase in the gross profit percentage in fiscal 2012 is attributed primarily to a favorable impact of approximately one percentage point from an increase in capacity absorption, and a favorable impact of approximately one percentage point from product mix. Gross profit was $9.8 million in fiscal 2010, or 83% of net sales. In fiscal 2011, compared to fiscal 2010, we had a favorable impact of increase in capacity absorption of approximately 0.5 percentage points and a favorable impact of product mix of approximately 0.4 percentage points, essentially offset by the negative impacts of changes in the currency exchange rates from our foreign currency-denominated sales and the additional costs in the first half of the fiscal year associated with the sourcing of our Urgent PC lead sets from a secondary supplier.

General and Administrative Expenses (G&A): G&A expenses of $3.7 million during fiscal 2012 increased $290,000 from $3.4 million during fiscal 2011. Included in fiscal 2012 is a charge of $412,000 for non-cash, share-based compensation expense, compared with $269,000 in fiscal 2011. Excluding share-based compensation charges, G&A expenses increased by $147,000, primarily because of a $86,000 increase in personnel costs. G&A expenses during fiscal 2011 increased $643,000 from $2.8 million during fiscal 2010. Included in fiscal 2011 is a charge of $269,000 for non-cash, share-based compensation expense, compared with $191,000 in fiscal 2010. Excluding share-based compensation charges, fiscal 2011 G&A expenses increased by $565,000, primarily because of a $186,000 increase in incentive compensation costs, a $196,000 increase in investor relations and related travel expenses, a $49,000 increase in legal and consulting fees, and a recovery of $57,000 in fiscal 2010 of a previously recorded bad debt expense.

Research and Development Expenses (R&D): R&D expenses increased to $1.9 million in fiscal 2012, from $1.7 million in fiscal 2011. The increase is attributed primarily to a $103,000 payment to a third party for costs it incurred in developing tooling for a product we no longer plan to commercialize, a $51,000 increase in compensation costs, and an increase of $67,000 in consulting costs, offset partially by a $70,000 decrease in human clinical trial costs. R&D expenses decreased to $1.7 million in fiscal 2011, from $1.8 million in fiscal 2010. The decrease is attributed primarily to a $141,000 decrease in spending for clinical studies, offset partially by a $52,000 increase in compensation costs and an increase of $53,000 in product design and regulatory costs.

Selling and Marketing Expenses (S&M): S&M expenses of $15.3 million in fiscal 2012 increased $5.2 million from $10.1 million in fiscal 2011. S&M expenses increased primarily because of a $3.5 million increase in compensation and a $200,000 increase in commission costs as a result of the increase in our U.S. field sales and support organization, an increase in travel expense of $587,000, and an increase of $578,000 related to marketing activities.

We expanded our U.S. field sales and support organization starting in our fiscal 2011 third quarter to capitalize on increased interest in our Urgent PC product after the new CPT code became effective in January 2011, and we

continued with that expansion in fiscal 2012. Accordingly, we incurred increased S&M expenses in fiscal 2012.

S&M expenses of $10.1 million in fiscal 2011 increased $2.5 million from $7.6 million in fiscal 2010. S&M expenses increased primarily because of a $1.4 million increase in compensation costs as a result of the increase in our U.S. field sales organization, an increase in travel expense of $425,000, an increase in commission expenses of $452,000, an increase in consulting costs of $180,000, and an increase in costs for attending sales conventions of $80,000. We incurred increased S&M expenses starting in the third and fourth quarters of fiscal 2011 with the increase in the U.S. field sales organization.

Amortization of Intangibles: Amortization of intangibles was $857,000 in fiscal 2012, $844,000 in fiscal 2011, and $846,000 in fiscal 2010. In April 2007, we acquired from CystoMedix, Inc., certain intellectual property assets related to the Urgent PC system for $4.7 million, which we are amortizing over six years.

Table of Contents

Other Income (Expense): Other income (expense) includes interest income, interest expense, foreign currency exchange and other non-operating costs when incurred. Net other income was $64,000, $78,000 and $41,000 for fiscal years 2012, 2011, and 2010, respectively.

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between us and our foreign subsidiaries. In fiscal 2012, and fiscal 2011, we recorded foreign currency exchange gain of $4,000 and $11,000, respectively, and in fiscal 2010 we recorded a foreign currency exchange loss of $38,000.

Income Tax Expense: In fiscal 2012, fiscal 2011, and fiscal 2010, we recorded income tax expense of $48,000, $29,000 and $41,000, respectively. Income tax expense is attributed to our Netherlands subsidiary and to the payment of minimum State taxes in the U.S. We cannot use our U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions.

Non-GAAP Financial Measures: The following table reconciles our operating loss calculated in accordance with accounting principles generally accepted in the U.S. (GAAP) to non-GAAP financial measures that exclude non-cash charges for share-based compensation, and depreciation and amortization expenses from gross profit, operating expenses and operating loss. The non-GAAP financial measures used by management and disclosed by us are not a substitute for, or superior to, financial measures and consolidated financial results calculated in accordance with GAAP, and you should carefully evaluate our reconciliations to non-GAAP. We may calculate our non-GAAP financial measures differently from similarly titled measures used by other companies. Therefore, our non-GAAP financial measures may not be comparable to those used by other companies. We have described the reconciliations of each of our non-GAAP financial measures described above to the most directly comparable GAAP financial measures.

We use these non-GAAP financial measures, and in particular non-GAAP operating loss, for internal managerial purposes and incentive compensation for senior management because we believe such measures are one important indicator of the strength and the operating performance of our business. Analysts and investors frequently ask us for this information. We believe that they use these measures to evaluate the overall operating performance of companies in our industry, including as a means of comparing period-to-period results and as a means of evaluating our results with those of other companies.

Our non-GAAP operating loss for fiscal 2012, 2011 and 2010 was approximately $2.5 million, $3.1 million and $1.7 million, respectively. The fiscal 2012 decrease in non-GAAP operating loss is attributed primarily to an increase in net sales which more than offset the increase in non-GAAP spending. The fiscal 2011 increase in non-GAAP operating loss is attributed primarily to an increase in non-GAAP spending, offset partially by an increase in net sales.

		Expense Adjustments			
	GAAP	Share-based Compensation	Depreciation	Amortization	
Year Ended March 31, 2012					
Gross Profit	$17,525,000	$22,000	$ 34,000		$17,581,000
% of net sales	85.2 %				85.5 %
Operating Expenses					
General & administrative	3,733,000	(412,000)	(163,000)		3,158,000
Research and development	1,905,000	(39,000)	(9,000)		1,857,000
Selling and marketing	15,296,000	(212,000)	(55,000)		15,029,000
Amortization	857,000			$ (857,000)	-

	21,791,000	(663,000)	(227,000)	(857,000)	20,044,000
Operating Loss	$(4,266,000)	$685,000	$ 261,000	$ 857,000	$(2,463,000)
Year Ended March 31, 2011					
Gross Profit	$11,401,000	$17,000	$52,000		$11,470,000
% of net sales	82.7 %				83.2 %
Operating Expenses					
General & administrative	3,443,000	(269,000)	(150,000)		3,024,000
Research and development	1,720,000	(27,000)	(10,000)		1,683,000
Selling and marketing	10,092,000	(121,000)	(63,000)		9,908,000
Amortization	844,000			$(844,000)	-
	16,099,000	(417,000)	(223,000)	(844,000)	14,615,000
Operating Loss	$(4,698,000)	$434,000	$275,000	$844,000	$(3,145,000)

Table of Contents

		Expense Adjustments			
	GAAP	Share-based Compensation	Depreciation	Amortization	Non-GAAP
Year Ended March 31, 2010					
Gross Profit	$9,804,000	$27,000	$ 58,000		$9,889,000
% of net sales	82.6 %				83.4 %
Operating Expenses					
General & administrative	2,799,000	(191,000)	(155,000)		2,453,000
Research and development	1,785,000	(49,000)	(13,000)		1,723,000
Selling and marketing	7,577,000	(147,000)	(67,000)		7,363,000
Amortization	846,000			$ (846,000)	-
	13,007,000	(387,000)	(235,000)	(846,000)	11,539,000
Operating Loss	$(3,203,000)	$414,000	$ 293,000	$ 846,000	$(1,650,000)

Liquidity and Capital Resources

Cash Flows.

At March 31, 2012, we had total cash and investments of $16.3 million, which includes $11.9 million of cash, cash equivalents and short-term investments and $4.4 million of long-term investments.

Cash used in operating activities was $3.1million in fiscal 2012, $3.4 million in fiscal 2011 and $1.9 million in fiscal 2010. We used this cash primarily to fund the operating loss, net of non-cash charges for depreciation, amortization and equity compensation, of $2.5 million, $3.1 million and $1.7 million in the respective years. We have continued to show an operating loss because we have continued to invest, primarily in sales and marketing, to grow our U.S. business. In addition to the use of cash for operating activities, we also used cash to fund the increase in net operating assets of $650,000 in fiscal 2012 and $297,000 in fiscal 2011, primarily for increases in receivables and inventory to support the increase in sales. In fiscal 2010 we used $167,000 for net operating activities to fund the increase in receivables and decrease in payables and accrued liabilities.

In fiscal 2012, we used $268,000 in investing activities to purchase property, plant and equipment compared with $229,000 in fiscal 2011, and $111,000 in fiscal 2010.

In fiscal 2012, we generated proceeds from financing activities of $209,000 from the exercise of stock options, compared with $17.4 million in fiscal 2011 from the net proceeds of $14.9 million from a public offering of our common stock and $2.2 million from the exercise of warrants we had issued in previous financing transactions.

Sources of Liquidity.

Uroplasty BV, our subsidiary, has an agreement with Rabobank of The Netherlands for a €500,000 (approximately $667,000) credit line secured by our facility in Geleen, The Netherlands. The bank charges interest on the loan at the rate of one percentage point over the Rabobank base interest rate (4.4% base rate on March 31, 2012), subject to a minimum interest rate of 3.50% per annum. We had no borrowings outstanding on this credit line at March 31, 2012 and March 31, 2011.

We believe we have sufficient liquidity to meet our needs for beyond the next twelve months. Although we have historically not generated cash from operations because we have yet to achieve profitability, we anticipate that we will become profitable and generate excess cash from operations prior to the full use of the current available cash and investments. To achieve this however, we must generate substantially more revenue than we have this year or in prior

years.

Our ability to achieve significant revenue growth will depend, in large part, on our ability to achieve widespread market acceptance for our products and successfully expand our business in the U.S., which in turn may be partially dependent upon re-establishing broader reimbursement for our Urgent PC product. We cannot guarantee that we will be entirely successful at this. If we fail to meet our projections of profitability and cash flow, or determine to use cash for matters we have not currently projected, we may need to again seek financing to meet our cash needs. We cannot assure you that such financing, if needed, will be available to us on acceptable terms, or at all.

Table of Contents

Commitments and Contingencies.

We expect to continue to incur costs for clinical studies to support our ongoing marketing efforts and to meet regulatory requirements. We also expect to continue to incur significant expenses to support our U.S. sales and marketing organization, and for regulatory activities. In fiscal 2013 we plan to start on two multiyear studies: a pilot clinical study in the U.S, for the use of our Urgent PC for the treatment of fecal incontinence and a clinical study and product design for a minimally invasive implantable product for treatment of OAB. We estimate we will spend $0.8 million in fiscal 2013for this.

Future payments under our contractual obligations as of March 31, 2012, consisting of royalties, purchase commitments, and operating leases, are summarized below:

		Payments Due by Period			
	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
Minimum royalty payments (a)	$117,000	$54,000	$63,000	$-	$-
Minimum purchase agreement (b)	531,000	531,000	-	-	-
Operating lease commitments (c)	438,000	204,000	224,000	10,000	-
Total contractual obligations	$1,086,000	$789,000	$287,000	$10,000	$-

(a) Under a royalty agreement we pay royalties of five percent of net sales of Macroplastique in countries where a patent is filed subject to a monthly minimum of $4,500. The royalties payable under this agreement will continue until certain patents referenced in the agreement expire in 2013 and 2015. Under a license agreement for the Macroplastique Implantation System, we pay a royalty of 10 Great Britain Pounds for each unit sold during the life of the patent. We recognized an aggregate of $383,000, $266,000 and $237,000 of royalty expense, under these agreements in fiscal 2012, 2011 and 2010, respectively.

(b) In our normal course of business we have commitments, generally for periods of less than twelve months, to purchase from various vendors finished goods and manufacturing components under issued purchase orders.

(c) In January 2006, we entered into a long-term lease with Liberty Property Limited Partnership for an 18,258 square foot facility for our U.S. headquarters located at 5420 Feltl Road, Minnetonka, Minnesota. The lease, effective May 1, 2006, has a term of 96 months, requires average annual minimum rent payments of approximately $140,000, and requires payments for operating expenses we estimate at approximately $90,000 over 12 months.

We have a defined benefit pension plan covering seven current and nineteen former employees in The Netherlands. We pay premiums to an insurance company to fund annuities for the current employees. We are responsible for funding additional annuities based on continued service and future salary increases. We closed this defined benefit plan for new employees in April 2005. As of that date, The Netherlands subsidiary established a defined contribution plan that now covers new employees. We also have a defined benefit pension plan for six former employees of our UK subsidiary. We closed this plan to further accrual for all employees effective December 31, 2004, and, effective March 2005, established a defined contribution plan that now covers new employees.

The following table presents the sensitivity of our funded status as of March 31, 2012, and fiscal 2013 pension expense to the following changes in key assumptions:

Assumption:	Increase/(Decrease) Funded Status at March 31, 2012	Increase/(Decrease) Fiscal 2013 Pension Expense
Increase in discount rate by 1 percentage point	$ 225,000	$ (20,000)
Decrease in discount rate by 1percentage point	(298,000)	23,000
Increase in estimated return on assets by 1 percentage point	n/a	(6,000)
Decrease of estimated return on assets by 1percentage point	n/a	6,000
Increase in inflation rate by 1 percentage point	(307,000)	54,000
Decrease in inflation rate by 1 percentage point	264,000	(46,000)
Increase in compensation increase by 1 percentage point	(214,000)	43,000
Decrease in compensation increase by 1 percentage point	4,000	(1,000)

Table of Contents

Product Liability. The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Any defects or risks that we have not yet identified with our products may give rise to product liability claims. Our existing $10 million of worldwide product liability insurance coverage may be inadequate to protect us from liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Cash Investments – The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk or availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including money market funds, U.S. government securities, and certain bank obligations. Our cash and cash equivalents as of March 31, 2012 include liquid money market accounts. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk.

Foreign Currency Exchange Risk – We are subject to exposures resulting from foreign currency exchange fluctuations in the normal course of business because of the global nature of our operations. Our primary exchange rate exposures are with the Euro and the British pound. The direct financial impact of foreign currency exchange includes the effect of translating profits from local currencies to U.S. dollars, the impact of currency fluctuations on the transfer of goods between our operations in the United States and abroad and transaction gains and losses. A stronger dollar generally has a negative impact on results from operations outside the United States, while a weaker dollar generally has a positive effect because our products are currently manufactured or sourced primarily from the United States.

In addition to the direct financial impact, foreign currency exchange has an indirect financial impact on our results, including the effect on sales volumes within local economies and the impact of any pricing actions we may take as a result of foreign exchange rate fluctuations. When the U.S. dollar weakens against foreign currencies, the dollar value of sales denominated in foreign currencies increases. When the U.S. dollar strengthens against foreign currencies, the dollar value of sales denominated in foreign currencies decreases. A hypothetical 10% change in the value of the U.S. dollar in relation to our foreign currency exposures would have had an impact of approximately $671,000 on our fiscal 2012 sales. This amount is not indicative of the hypothetical net earnings impact due to the partially offsetting impacts on the related cost of goods sold and operating expenses in the applicable foreign currencies.

Item 8. Financial Statements and Supplementary Data

The information contained in Exhibit 13 under the headings “Consolidated Statements of Operations,” “Consolidated Balance Sheets,” “Consolidated Statements of Shareholders’ Equity and Comprehensive Loss,” “Consolidated Statements of Cash Flows,” “Notes to Consolidated Financial Statements” and “Report of Independent Registered Public Accounting Firms” is incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system was designed to provide reasonable assurance to our management and Board of Directors regarding the preparation and fair presentation of our published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in "Internal Control — Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on our evaluation under the framework in "Internal Control — Integrated Framework," our management concluded that our internal control over financial reporting was effective as of March 31, 2012.

Table of Contents

The effectiveness of our internal control over financial reporting as of March 31, 2012, has been audited by Grant Thornton LLP, the independent registered public accounting firm who also has audited our consolidated financial statements as of and for the year ended March 31, 2012, included in this Form 10-K. Grant Thornton's attestation report on the effectiveness of our internal control over financial reporting appears on page F-2 of this Form 10-K.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fiscal quarter ended March 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Table of Contents

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The information contained under the headings “Election of Directors,” “Executive Officers” and “Section 16 Beneficial Ownership Reporting Compliance” in the Proxy Statement is incorporated herein by reference.

Item 11. Executive Compensation

The information contained under the heading “Executive Compensation” and “Director Compensation” in the Proxy Statement is incorporated herein by reference.

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

The information contained under the heading “Principal Shareholders” in the Proxy Statement 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 Party Transactions,” if any, in the Proxy Statement is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

This information contained under the headings Auditing Matters “--Fees,” “ --All Other Fees” and “--Pre-Approval Process” in the Proxy Statement is incorporated herein by reference.

Table of Contents

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this Annual Report on Form 10-K:

1. Consolidated Financial Statements:

2. Financial Statement Schedules:

Schedule II – Valuation and Qualifying Accounts

	Balance at beginning of fiscal year	Additions charged to costs and expenses	Written off, less recoveries	Effects of foreign currency fluctuations	Balance at end of fiscal year
Allowance for doubtful accounts and sales returns					
Fiscal year ended March 31, 2012	$79,000	$110,000	$(87,000)	$(1,000)	$101,000
Fiscal year ended March 31, 2011	78,000	37,000	(36,000)	-	79,000
Fiscal year ended March 31, 2010	177,000	19,000	(126,000)	8,000	78,000

3. Exhibits

(a) Exhibits incorporated by reference.

Number	Description
3.1	Amended & Restated By Laws of Uroplasty, Inc. (Incorporated by reference to Exhibit 3.1 to Registrant's Form 8-K filed dated November 20, 2009)
3.2	Restated Articles of Incorporation of Uroplasty, Inc. (Incorporated by reference to Exhibit 3.1 to Registrant's Registration Statement on Form SB-2 filed October 18, 2007 (File No. 333-146787))
10.1	Settlement Agreement and Release dated November 30, 1993 by and between Bioplasty, Inc., Bio-Manufacturing, Inc., Uroplasty, Inc., Arthur A. Beisang, Arthur A. Beisang III, MD and Robert A. Ersek, MD (Incorporated by reference to Exhibit 6.1 to Registrant's Registration Statement on Form 10SB filed July 10, 1996)

10.2*	Employment Agreement between Uroplasty, Inc. and Susan Holman dated December 7, 1999. (Incorporated by reference to Exhibit 10.13 to Registrant's Form 10-KSB for the year ended March 31, 2000 filed June 26, 2000)
10.3*	Employment Agreement between Uroplasty, Inc. and Larry Heinemann dated December 7, 1999. (Incorporated by reference to Exhibit 10.14 to Registrant's Form 10-KSB for the year ended March 31, 2000, filed June 26, 2000)
10.4	Agreement, dated October 14, 1998, by and between Uroplasty, Inc. and Samir M. Henalla (pertaining to Macroplastique Implantation System). (Incorporated by reference to Exhibit 10.15 to Registrant's Form 10-KSB/A for the year ended March 31, 2001, filed March 27, 2002)

Table of Contents

10.5*	2002 Employee Stock Option Plan (Incorporated by reference to the copy filed as Appendix B to the Proxy Statement filed with the SEC on August 1, 2002)
10.6*	Employment Agreement between Uroplasty, Inc. and Mr. Marc Herregraven dated November 15, 2002. (Incorporated by reference to Exhibit 10.15 to Registrant's Form 10-KSB for the year ended March 31, 2003, filed May 20, 2003)
10.7*	Employment Agreement between Uroplasty, Inc. and Mahedi A. Jiwani dated November 14, 2005 (Incorporated by reference to Exhibit 10.24 to Registrant's Form 10-QSB filed November 14, 2005)
10.8*	Employment Agreement between Uroplasty, Inc. and David B. Kaysen dated May 17, 2006 (Incorporated by reference to Exhibit 10.30 to Registrant's Form 10-KSB filed June 29, 2006)
10.9*	2006 Amended Stock and Incentive Plan (Incorporated by reference to the copy attached as Appendix A to the Company's Definitive Proxy Statement filed on July 25, 2008)
10.10*	Amendment to the Employment Agreement between Uroplasty, Inc. and Mr. David B. Kaysen. (Incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K dated April 26, 2011)
10.11	Lease Agreement between Uroplasty, Inc. and Liberty Property Limited Partnership dated January 20, 2006 (Incorporated by reference to Exhibit 10.25 to Registrant's Form 8-K filed January 24, 2006)
10.12	Form of Purchase Agreement, dated as of March 15, 2007, by and between Uroplasty, Inc. and CystoMedix, Inc. (Incorporated by reference to Exhibit 10.36 to Registrant's Form 8-K filed March 20, 2007
14.1	Revised Code of Ethics titled Code of Business Conduct and Ethics for Directors, Officers and Employees (Incorporated by reference to Exhibit 14.1 to Registrant's Form 8-K filed April 12, 2007)

(c) Exhibits filed herewith.

Number	Description
10.13*	Employment Agreement between Uroplasty, Inc. and Nancy Kolb dated May 22, 2012
13	Financial Statements
21.0	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm – Grant Thornton LLP
24.1	Power of Attorney
31	Certifications by the CEO and CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications by the CEO and CFO pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
99.1	Press Release dated May 24, 2012
101	Financial statements from the Annual Report on Form 10-K for the year ended March 31, 2012, formatted in Extensible Business Reporting Language: (i) Financial Statement Schedules, (ii) the Consolidated Balance Sheets, (iii) the Consolidated Statements of Operations, (iv) the Consolidated Statements of Shareholders' Equity and Comprehensive Loss, (v) the Consolidated Statements of Cash Flows and (vi) the Notes to Consolidated Financial Statements.

* Management contract, compensation plan or arrangement

Table of Contents

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: May 24, 2012

UROPLASTY, INC.

By /s/ David B. Kaysen
David B. Kaysen
President and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title / Capacity	Date
/s/ David B. Kaysen David B. Kaysen	President, Chief Executive Officer and Director (Principal Executive Officer)	May 24, 2012
/s/ Mahedi A. Jiwani Mahedi A. Jiwani	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	May 24, 2012
/s/ R. Patrick Maxwell* R. Patrick Maxwell	Director	May 24, 2012
/s/ Thomas E. Jamison* Thomas E. Jamison	Director	May 24, 2012
/s/ Lee A. Jones* Lee A. Jones	Chairman of the Board of Directors	May 24, 2012
/s/ Robert C. Kill* Robert Kill	Director	May 24, 2012
/s/ James P. Stauner* James P. Stauner	Director	May 24, 2012
/s/ Sven A. Wehrwein* Sven A. Wehrwein	Director	May 24, 2012

*Mahedi A. Jiwani, by signing his name hereto, does hereby sign this document on behalf of each of the above named directors of the registrant pursuant to powers of attorney duly executed by such persons.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements
March 31, 2012 and 2011

TABLE OF CONTENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Uroplasty, Inc.

We have audited the accompanying consolidated balance sheets of Uroplasty, Inc. (a Minnesota corporation) and subsidi−aries (together "the Company") as of March 31, 2012 and 2011, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended March 31, 2012. Our audits of the basic consolidated financial state−ments 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 Com−pany'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 mis−statement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclo−sures in the financial statements. An audit also includes assessing the accounting principles used and significant esti−mates 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 Uroplasty, Inc. and subsidiaries as of March 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 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 March 31, 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 May 24, 2012 expressed an unqualified opinion thereon.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
May 24, 2012

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Uroplasty, Inc.

We have audited Uroplasty, Inc. (a Minnesota corporation) and subsidiaries' (together "the Company") internal control over financial reporting as of March 31, 2012, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, 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.

In our opinion, Uroplasty, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of March 31, 2012, based on criteria established in the 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 Uroplasty, Inc. and subsidiaries as of March 31, 2012 and 2011, and the related consolidated statements of operations, shareholders' equity and comprehensive loss, and cash flows for each of the three years in the period ended March 31, 2012, and our report dated May 24, 2012 expressed an unqualified opinion thereon.

/s/ Grant Thornton LLP

Minneapolis, Minnesota
May 24, 2012

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

March 31,

	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	$4,653,226	$6,063,573
Short-term investments	7,200,901	8,020,577
Accounts receivable, net	2,704,434	2,085,262
Inventories	698,742	677,960
Other	363,639	348,100
Total current assets	15,620,942	17,195,472
Property, plant, and equipment, net	1,171,979	1,210,542
Intangible assets, net	945,880	1,725,136
Long-term investments	4,429,140	5,508,701
Deferred tax assets	122,872	87,031
Total assets	$22,290,813	$25,726,882

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
March 31,

	2012	2011
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$593,585	$658,107
Current portion - deferred rent	35,000	35,000
Income tax payable	17,892	6,901
Accrued liabilities:		
Compensation	1,576,147	1,597,657
Other	316,995	247,451
Total current liabilities	2,539,619	2,545,116
Deferred rent – less current portion	42,043	77,272
Accrued pension liability	474,396	475,845
Total liabilities	3,056,058	3,098,233
Commitments and contingencies	-	-
Shareholders' equity:		
Common stock $.01 par value; 40,000,000 shares authorized, 20,808,532 and 20,664,332 shares issued and outstanding at March 31, 2012 and 2011, respectively.	208,085	206,643
Additional paid-in capital	54,906,670	54,014,368
Accumulated deficit	(35,515,835)	(31,265,464)
Accumulated other comprehensive loss	(364,165)	(326,898)
Total shareholders' equity	19,234,755	22,628,649
Total liabilities and shareholders' equity	$22,290,813	$25,726,882

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended March 31,

	2012	2011	2010
Net sales	$20,561,714	$13,787,032	$11,863,202
Cost of goods sold	3,036,967	2,386,431	2,058,855
Gross profit	17,524,747	11,400,601	9,804,347
Operating expenses			
General and administrative	3,732,623	3,442,952	2,799,753
Research and development	1,905,366	1,719,532	1,785,405
Selling and marketing	15,296,217	10,092,062	7,576,776
Amortization	856,995	843,602	845,553
	21,791,201	16,098,148	13,007,487
Operating loss	(4,266,454)	(4,697,547)	(3,203,140)
Other income (expense)			
Interest income	60,072	72,426	92,736
Interest expense	(57)	(5,067)	(14,476)
Foreign currency exchange gain (loss)	3,780	10,722	(37,552)
	63,795	78,081	40,708
Loss before income taxes	(4,202,659)	(4,619,466)	(3,162,432)
Income tax expense	47,712	28,837	41,379
Net loss	$(4,250,371)	$(4,648,303)	$(3,203,811)
Basic and diluted loss per common share	$(0.21)	$(0.25)	$(0.21)
Weighted average common shares outstanding:			
Basic and diluted	20,689,819	18,874,009	14,944,354

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS
Years ended March 31, 2012, 2011 and 2010

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive Income	Total Shareholders'
	Shares	Amount	Capital	Deficit	(Loss)	Equity
Balance at March 31, 2009	14,946,540	$149,465	$35,763,619	$(23,413,350)	$ (191,157)	$12,308,577
Share-based compensation expense	-	-	414,507	-	-	414,507
Comprehensive loss	-	-	-	(3,203,811)	(304,746)	(3,508,557)
Balance at March 31, 2010	14,946,540	149,465	36,178,126	(26,617,161)	(495,903)	9,214,527
Proceeds from public offering, net of costs of $1,182,941	4,600,000	46,000	14,871,059	-	-	14,917,059
Share-based consulting and compensation expense	72,900	729	433,425	-	-	434,154
Proceeds from exercise of warrants, net of costs of $3,668	886,000	8,860	2,190,322	-	-	2,199,182
Proceeds from exercise of stock options, net of 1,608 shares returned for payment of related income taxes	158,892	1,589	341,436	-	-	343,025
Comprehensive income (loss)	-	-	-	(4,648,303)	169,005	(4,479,298)
Balance at March 31, 2011	20,664,332	206,643	54,014,368	(31,265,464)	(326,898)	22,628,649
Share-based consulting and compensation expense	50,200	502	684,417	-	-	684,919
Proceeds from exercise of stock options	94,000	940	207,885	-	-	208,825
Comprehensive loss	-	-	-	(4,250,371)	(37,267)	(4,287,638)
Balance at March 31, 2012	20,808,532	$208,085	$54,906,670	$(35,515,835)	$ (364,165)	$19,234,755

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended March 31,

	2012	2011	2010
Cash flows from operating activities:			
Net loss	$(4,250,371)	$(4,648,303)	$(3,203,811)
Adjustments to reconcile net loss to net cash used in operations:			
Depreciation and amortization	1,118,243	1,119,227	1,138,077
Loss on disposal of equipment	8,447	5,358	853
Amortization of premium on marketable securities	35,277	18,910	-
Share-based consulting expense	5,448	11,261	-
Share-based compensation expense	679,471	422,893	414,507
Deferred income taxes	(40,116)	26,192	(39,741)
Deferred rent	(35,228)	(35,228)	(35,076)
Changes in operating assets and liabilities:			
Accounts receivable, net	(653,110)	(752,970)	(56,052)
Inventories	(29,719)	(328,754)	172,723
Other current assets	(17,510)	(85,529)	(42,827)
Accounts payable	(59,025)	170,326	(127,355)
Accrued liabilities	63,981	711,832	(152,700)
Accrued pension liability, net	45,843	(11,680)	39,159
Net cash used in operating activities	(3,128,369)	(3,376,465)	(1,892,243)
Cash flows from investing activities:			
Proceeds from maturity of available-for-sale marketable securities	10,018,252	2,261,568	-
Proceeds from maturity of held-to-maturity marketable securities	3,740,000	5,000,000	5,500,000
Purchases of available-for-sale marketable securities	(3,046,270)	(12,318,915)	-
Purchases of held-to-maturity marketable securities	(8,840,000)	(5,000,000)	(4,500,000)
Purchases of property, plant and equipment	(267,944)	(229,131)	(111,154)
Payments for intangible assets	(77,738)	(35,643)	2,800
Net cash provided by (used in) investing activities	1,526,300	(10,322,121)	891,646
Cash flows from financing activities:			
Net proceeds from public offering of common stock	-	14,917,059	-
Net proceeds from exercise of warrants and options	208,825	2,542,207	-
Net cash provided by financing activities	208,825	17,459,266	-
Effect of exchange rates on cash and cash equivalents	(17,103)	(8,376)	35,567
Net increase (decrease) in cash and cash equivalents	(1,410,347)	3,752,304	(965,030)
Cash and cash equivalents at beginning of year	6,063,573	2,311,269	3,276,299
Cash and cash equivalents at end of year	$4,653,226	$6,063,573	$2,311,269
Supplemental disclosure of cash flow information:			
Cash paid during the year for interest	$57	$17	$7,697
Cash paid during the year for income tax	39,005	17,549	135,032

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2012 and 2011

1. Summary of Significant Accounting Policies

Nature of Business. We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our primary focus is on two products: our Urgent PC® Neuromodulation System, which we believe is the only FDA-cleared minimally invasive, office-based neuromodulation therapy for the treatment of overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence; and Macroplastique® Implants, a urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency (ISD). Outside of the U.S., our Urgent PC Neuromodulation System is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence and vesicoureteral reflux.

Our primary focus is on growth in the U.S. market, which we entered in 2005. Prior to that, essentially all of our business was outside of the U.S. We believe the U.S. market presents a significant opportunity for growth in sales of our products.

The Urgent PC Neuromodulation System uses percutaneous tibial nerve stimulation (PTNS) to deliver to the tibal nerve an electrical pulse that travels to the sacral nerve plexus, a control center for pelvic floor and bladder function. We have received regulatory clearances for sale of the Urgent PC System in the United States, Canada and Europe. We launched sales of our second generation Urgent PC System in late 2006. We have intellectual property rights relating to key aspects of our neurostimulation therapy, and we believe our intellectual property portfolio provides us a competitive advantage.

We have sold Macroplastique for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from the FDA pre-market approval for the use of Macroplastique to treat adult female stress urinary incontinence. We began marketing Macroplastique in the United States in 2007.

Principles of Consolidation. The consolidated financial statements include the accounts of Uroplasty, Inc. and its wholly owned foreign subsidiaries. We have eliminated all significant intercompany accounts and transactions in consolidation.

Revenue Recognition. We recognize revenue when persuasive evidence of an arrangement exists, title and risk of ownership have passed, the sales price is fixed or determinable and collectability is reasonably assured. Generally, these criteria are met at the time the product is shipped to the customer. We include shipping and handling charges billed to customers in net sales, and include such costs incurred by us in cost of goods sold. Typically our agreements contain no customer acceptance provisions or clauses. We sell our products to end users and to distributors. Payment terms range from prepayment to 120 days. The distributor payment terms are not contingent on the distributor selling the product to end users. Customers do not have the right to return unsold products except for warranty claims. We offer customary product warranties. During fiscal 2012, 2011 and 2010, no customers accounted for 10% or more of our net sales. We present our sales in our statement of operations net of taxes, such as sales, use, value-added and certain excise taxes, collected from the customers and remitted to governmental authorities.

Use of Estimates. The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and 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. Actual results could differ from these estimates. Our significant

accounting policies and estimates include revenue recognition, accounts receivable, valuation of inventory, foreign currency translation/transactions, the determination of recoverability of long-lived and intangible assets, share-based compensation, defined benefit pension plans, and income taxes.

Disclosures About Fair Value of Financial Instruments. Estimates of fair value for financial assets and liabilities are based on the framework established in the accounting guidance for fair value measurements. The framework defines fair value, provides guidance for measuring fair value and requires certain disclosures. The framework prioritizes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The following three broad levels of inputs may be used to measure fair value under the fair value hierarchy:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Table of Contents

- Level 3: Significant unobservable inputs that cannot be corroborated by observable market data and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

If the inputs used to measure the financial assets and liabilities fall within more than one of the different levels described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

The following table provides the assets carried at fair value measured on a recurring basis at March 31:

Asset Class	Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
2012				
Short-term investments:				
U.S. Government and Agency debt securities	$ 1,001,000	$ -	$ 1,001,000	$ -
Long-term investments:				
U.S. Government and Agency debt securities	2,029,000	-	2,029,000	-
2011				
Short-term investments:				
U.S. Government and Agency debt securities	$ 4,520,000	$ -	$ 4,520,000	$ -
Long-term investments:				
U.S. Government and Agency debt securities	5,508,000	-	5,508,000	-

U.S. Government and U.S. Government Agency debt securities. Our debt securities consist of bonds, notes and treasury bills with risk ratings of AAA/Aaa and maturity dates within two years from date of purchase. The estimated fair value of these securities is based on valuations provided by external investment managers.

We measure the fair value of our tangible fixed assets and other intangible assets whenever events or circumstances indicate that the carrying value of those assets may not be recoverable. We assess recoverability by estimating the future cash flows expected to be generated by those assets. We had no significant remeasurements of such assets or liabilities to fair value during fiscal 2012, 2011, and 2010.

Our financial instruments, other than those presented in the disclosures above, include cash, receivables, inventories, accounts payable and other payables, and their carrying values approximate their fair values based of the short-term nature of these instruments.

Cash, Cash Equivalents and Marketable Securities. We consider all cash on-hand and highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. We classify marketable securities having original maturities of more than three months when purchased and remaining maturities of one year or less as short-term investments and marketable securities with remaining maturities of more than one year as long-term investments. We further classify marketable securities as either held-to-maturity or available-for-sale. We classify marketable securities as held-to-maturity when we believe we have the ability and intent to hold such securities to their scheduled maturity dates. All other marketable securities are classified as available-for-sale. We have not

designated any of our marketable securities as trading securities.

We carry held-to-maturity marketable securities at their amortized cost and available-for-sale marketable securities at their fair value and report any unrealized appreciation or depreciation in the fair value of available-for-sale marketable securities in accumulated other comprehensive income (loss). We monitor our investment portfolio for any decline in fair value that is other-than-temporary and record any such impairment as an impairment loss. We recorded no impairment losses for other-than-temporary declines in the fair value of marketable securities in fiscal 2012, 2011, and 2010.

Table of Contents

Cash and cash equivalents include highly liquid money market funds and debt securities with original maturities of three months or less of $3.3 million and $5.8 million at March 31, 2012 and March 31, 2011, respectively. Money market funds present negligible risk of changes in value due to changes in interest rates, and their cost approximates their fair market value. We maintain cash in bank accounts, which, at times, may exceed federally insured limits. We have not experienced any losses in such accounts. Cash and cash equivalents held in foreign bank accounts totaled $858,000 and $570,000 at March 31, 2012 and 2011, respectively.

The amortized cost and fair value of our marketable securities classified as available-for-sale at March 31 are summarized as follows:

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
2012				
Short-term investments:				
U.S. Government and Agency debt securities	$ 1,001,000	$ -	$ -	$ 1,001,000
Long-term investments:				
U.S. Government and Agency debt securities	2,030,000	-	(1,000)	2,029,000
Total	$ 3,031,000	$ -	$ (1,000)	$ 3,030,000
2011				
Short-term investments:				
U.S. Government and Agency debt securities	$ 4,520,000	$ 1,000	$ -	$ 4,521,000
Long-term investments:				
U.S. Government and Agency debt securities	5,518,000	-	(10,000)	5,508,000
Total	$ 10,038,000	$ 1,000	$ (10,000)	$ 10,029,000

All our available-for-sale marketable securities mature within two years from the date of purchase.

Short-term investments include held-to-maturity certificates of deposit of $6.2 million and $3.5 million at March 31, 2012 and 2011, respectively. Long-term investments include held-to-maturity certificates of deposit that mature within two years from the date of purchase of $2.4 million at March 31, 2012. There were no long-term held-to-maturity investments at March 31, 2011. Due to the negligible risk of changes in value due to changes in interest rates and the short-term nature of these investments, their cost approximates their fair market value.

Accounts Receivable. We grant credit to our customers in the normal course of business and, generally, do not require collateral or any other security to support amounts due. If necessary, we have an outside party assist us with performing credit and reference checks and establishing credit limits for the customer. Accounts outstanding longer than the contractual payment terms, are considered past due. We carry our accounts receivable at the original invoice amount less an estimate made for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts by considering a number of factors, including the length of time accounts receivable are past due, customer financial condition and ability to pay the obligation, historical and expected credit loss experience, and the condition of the general economy and the industry as a whole. We write off accounts receivable when deemed uncollectible. We record recoveries of accounts receivable previously written off

when received. We are not always able to timely anticipate changes in the financial condition of our customers and if circumstances related to these customers deteriorate, our estimates of the recoverability of accounts receivable could be materially affected and we may be required to record additional allowances. Alternatively, if more allowances are provided than are ultimately required, we may reverse a portion of such provisions in future periods based on the actual collection experience. Historically, the accounts receivable balances we have written off have generally been within our expectations. The allowance for doubtful accounts and sales returns was $101,000 and $79,000 at March 31, 2012 and 2011, respectively.

Table of Contents

Inventories. We state inventories at the lower of cost or market using the first-in, first-out method. We provide lower of cost or market reserves for slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. Inventories consist of the following at March 31:

	2012	2011
Raw materials	$ 219,000	$ 233,000
Work-in-process	1,000	9,000
Finished goods	479,000	436,000
	$ 699,000	$ 678,000

Property, Plant, and Equipment. We carry property, plant, and equipment, including leasehold improvements, at cost, less accumulated depreciation which consist of the following at March 31:

	2012	2011
Land	$ 163,000	$ 173,000
Building	745,000	788,000
Leasehold improvements	376,000	351,000
Internal use software	468,000	359,000
Equipment	1,315,000	1,296,000
	3,067,000	2,967,000
Less accumulated depreciation	(1,895,000)	(1,756,000)
	$ 1,172,000	$ 1,211,000

We provide for depreciation using the straight-line method over useful lives of three to seven years for equipment and 40 years for the building. We charge maintenance and repairs to expense as incurred. We capitalize renewals and improvements and depreciate them over the shorter of their estimated useful service lives or the remaining lease term. We recognized depreciation expense of approximately $261,000, $276,000 and $293,000 in fiscal 2012, 2011 and 2010, respectively.

We capitalized internal use software and web site development costs of $109,000, $54,000, and $17,000 in fiscal 2012, 2011, and 2010, respectively. The net book value of our capitalized software for internal use was $125,000 and $68,000 at March 31, 2012 and 2011, respectively.

Intangible Assets. Our intangible assets are comprised of patents which we amortize on a straight-line basis over their estimated useful lives of six years.

	Gross Carrying Amount	Accumulated Amortization	Net value
March 31, 2012	$ 5,586,000	$ 4,640,000	$ 946,000
March 31, 2011	5,508,000	3,783,000	1,725,000

At March 31, 2012, we estimate the following annual amortization for these assets in subsequent fiscal years:

2013	$862,000
2014	23,000
2015	22,000
2016	20,000
2017 and beyond	19,000
	$946,000

Table of Contents

Impairment of Long-Lived Assets. Long-lived assets at March 31, 2012 consisted of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that we may not recover the carrying amount of an asset. We measure recoverability of assets held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows we expect to generate by the asset. If we consider such assets impaired, we measure the impairment recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We completed our impairment analysis and concluded there was no impairment in fiscal 2012, 2011, and 2010.

Product Warranty. We warrant our products to be free from defects in material and workmanship under normal use and service for a period of twelve months after the date of sale. Under the terms of these warranties, we repair or replace products we deem defective due to material or workmanship. We recognized warranty expense of $37,000, $15,000 and $6,000 for the years ended March 31, 2012, 2011 and 2010, respectively.

Deferred Rent. We entered into an 8-year operating lease agreement, effective May 2006, for our corporate facility in Minnesota. As part of the agreement, the landlord provided an incentive of $280,000 for leasehold improvements. We recorded this incentive as deferred rent and are amortizing it as a reduction in lease expense over the lease term.

Foreign Currency Translation. We translate all assets and liabilities using period-end exchange rates. We translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders' equity. We recognize foreign currency transaction gains and losses in our consolidated statements of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders' equity.

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated intercompany obligations between us and our foreign subsidiaries. All intercompany balances are revolving in nature and we do not deem any portion of them to be long-term. We recognized foreign currency exchange gain (loss) of approximately $4,000, $11,000 and $(38,000) for the years ended March 31, 2012, 2011 and 2010, respectively.

Income Taxes. We account for income taxes using the asset and liability method. The asset and liability method provides that deferred tax assets and liabilities be recorded based on the differences between the tax basis of assets and liabilities and their carrying amounts for financial reporting purposes. We reduce deferred tax assets by a valuation allowance, when we believe it is more likely than not that some portion or all of the deferred tax assets will not be realized.

ASC 740 "Accounting for Income Taxes" , prescribes a recognition threshold and a measurement attribute for financial statement recognition of tax positions we take or expect to take in a tax return. It is management's responsibility to determine whether it is "more-likely-than-not" that a taxing authority will sustain a tax position upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. We have reviewed all income tax positions taken or that we expect to take for all open tax years and have determined that our income tax positions are appropriately stated and supported for all open years. Accordingly, we have no reserve for uncertain tax positions in our consolidated financial statements.

Under our accounting policies we recognize interest and penalties accrued on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. As of March 31, 2012 and 2011, we

recorded no accrued interest or penalties related to uncertain tax positions.

We recorded income tax expense of $48,000, $29,000 and $41,000 for the years ended March 31, 2012, 2011 and 2010, respectively. Income tax expense is attributed to our Netherlands subsidiary and to the payment of minimum State taxes in the U.S. We cannot use our U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions.

The fiscal tax years 2008 through 2012 remain open to examination by the Internal Revenue Service and various state taxing jurisdictions to which we are subject. In addition, we are subject to examination by certain foreign taxing authorities for which the fiscal years 2009 through 2012 remain open for examination.

As of March 31, 2012, we have generated approximately $30 million in U.S. net operating loss carryforwards that we cannot use to offset taxable income in foreign jurisdictions. We recognize a valuation allowance when we determine it is more likely than not that we will not realize a portion of the deferred tax asset. We have established a valuation allowance for all U.S. and certain foreign deferred tax assets due to the uncertainty that we will generate enough income in those taxing jurisdictions to utilize the assets.

Table of Contents

In addition, future utilization of NOL carryforwards are subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. We believe that each of the issuances of our common stock in December 2006 and July 2010 resulted in an "ownership change" under Section 382. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 and after December 2006 and prior to July 2010 is limited.

Basic and Diluted Net Loss per Common Share. We calculate basic per common share amounts by dividing net loss by the weighted-average common shares outstanding. For calculating diluted per common share amounts, we add additional shares to the weighted-average common shares outstanding for the assumed exercise of stock options and warrants and vesting of restricted shares, if dilutive. Because we had a net loss in fiscal 2012, 2011 and 2010, the following options outstanding and unvested restricted stock to purchase shares of our common stock were excluded from diluted net loss per common share because of their anti-dilutive effect, and therefore, basic net loss per common share equals dilutive net loss per common share:

	Number of options and unvested restricted stock	Range of exercise prices
Years ended:		
March 31, 2012	2,153,000	$ 0.77 - $8.93
March 31, 2011	2,121,000	$ 0.71 - $6.61
March 31, 2010	4,104,000	$ 0.71 - $5.19

Advertising Expenses. Advertising costs are expensed as incurred. We expensed $571,000, $181,000 and $189,000 in fiscal 2012, 2011 and 2010, respectively.

2. Notes Payable

We had no outstanding notes payable at March 31, 2012 or March 31, 2011.

Uroplasty BV, our subsidiary, has an agreement with Rabobank of The Netherlands for a €500,000 (approximately $667,000) credit line secured by our facility in Geleen, The Netherlands. The bank charges interest on the loan at the rate of one percentage point over the Rabobank base interest rate (4.4% base rate on March 31, 2012), subject to a minimum interest rate of 3.5% per annum. At March 31, 2012 and 2011, we had no borrowings outstanding on this credit line.

3. Shareholders' Equity

Share-based Compensation. At March 31, 2012, we had one active plan (2006 Amended Stock and Incentive Plan) for share-based compensation grants. Under the plan, if we have a change in control, all outstanding grants, including those subject to vesting or other performance targets, fully vest immediately. On September 18, 2008, our shareholders amended this plan to increase the number of reserved shares of our common stock for share-based grants to 2,700,000, and 1,141,000 shares remain available for grant at March 31, 2012. We grant option awards with an exercise price equal to the closing market price of our stock at the date of the grant. We have options outstanding to purchase 1,183,000 shares of common stock granted under this plan. Options granted under this plan generally expire over a period ranging from five to seven years from date of grant and vest at varying rates ranging up to three years.

We have fully vested options outstanding to purchase 900,000 shares of common stock, not granted under the 2006 plan, which expire up to ten years from date of grant.

We grant options at the discretion of our directors. The plans generally provide for the exercise of options during a limited period following termination of employment, death or disability.

We recognize share-based compensation expense in the statement of operations based on the fair value of the share-based payment over the requisite service period. We incurred a total of approximately $685,000, $434,000 and $415,000 in share-based compensation expense (inclusive of $5,000, $11,000 and $0, respectively, for grants to consultants) in fiscal 2012, 2011 and 2010, respectively.

Table of Contents

We determine the fair value of the option awards using the Black-Scholes option pricing model. We used the following weighted-average assumptions to value the options granted during the years ended March 31:

	2012		2011		2010	
Expected life, in years	5.32		5.25		4.82	
Risk-free interest rate	1.57	%	1.76	%	2.74	%
Expected volatility	90.08	%	91.13	%	94.21	%
Expected dividend yield	0	%	0	%	0	%

The expected life selected for options granted represents the period of time we expect options to be outstanding based on historical data of option holder exercise and termination behavior for similar grants. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury rate over the expected life at the time of grant. Expected volatility is based upon historical volatility of our stock. We estimate the forfeiture rate for stock awards to range from 0% to 13.0% in fiscal 2012 based on our historical experience. The expected life of the options is based on the historical life of previously granted options which are generally held to maturity.

The following table summarizes the activity related to our stock options in fiscal 2010, 2011 and 2012:

	Number of shares	Weighted average exercise price	Weighted average grant date fair value	Aggregate intrinsic value	Weighted average remaining life in years
Balance at March 31, 2009	2,135,000				
Options granted	383,000		$ 0.60		
Options surrendered	(480,000)				
Balance at March 31, 2010	2,038,000				
Options granted	229,000		3.49		
Options exercised	(161,000)			$ 502,000	
Options surrendered	(40,000)				
Balance at March 31, 2011	2,066,000	$ 3.39			
Options granted	140,000	6.66	4.70		
Options exercised	(94,000)	2.22		430,000	
Options surrendered	(29,000)	5.36			
Balance at March 31, 2012	2,083,000	$ 3.64		$ 968,000	2.96
Options exercisable at March 31, 2012	1,838,000	$ 3.34		$ 968,000	2.57

The total fair value of stock options vested during fiscal 2012, 2011 and 2010 was $398,000, $221,000 and $567,000 respectively.

We received net proceeds of $209,000 from the exercise of stock options in fiscal 2012.

We grant restricted shares at the discretion of our directors with vesting terms ranging from six months to four years. The following table summarizes the activity related to our restricted stock in fiscal 2010, 2011 and 2012:

	Number of Shares	Weighted average grant date fair value	Weighted average remaining life in years	Aggregate intrinsic value
Balance at March 31, 2009	14,000			
Shares vested	(14,000)			$ 44,000
Balance at March 31, 2010	-			
Shares granted	73,000	$ 4.76		
Shares vested	(18,000)			75,000
Balance at March 31, 2011	55,000	4.96		
Shares granted	50,000	6.80		
Shares vested	(35,000)	4.91		170,000
Balance at March 31, 2012	70,000	$ 6.30	0.95	$ 443,000

Table of Contents

The aggregate intrinsic value shown above for the restricted shares represents the total pre-tax value based on the closing price of our Company's common stock on the grant date.

At March 31, 2012, we had approximately $996,000 of unrecognized share-based compensation cost, net of estimated forfeitures, related to stock options and restricted shares that we expect to recognize over a weighted-average requisite service period of approximately two years.

Warrants. The following table summarizes the activity during fiscal 2010, 2011 and 2012 related to warrants to purchase our common shares:

	Number of shares	Weighted average exercise price
Outstanding at March 31, 2009 and 2010	2,067,000	
Warrants expired in fiscal 2011	(1,181,000)	
Warrants exercised in fiscal 2011	(886,000)	$ 2.49
Outstanding at March 31, 2011 and 2012	-	

Other Comprehensive Loss. Other comprehensive loss for the years ended March 31 consists of net loss, accumulated translation adjustment, and pension related items as follows:

	2012	2011	2010
Net loss	$ (4,250,000)	$ (4,648,000)	$ (3,204,000)
Items of other comprehensive income (loss):			
Translation adjustment	(80,000)	58,000	25,000
Unrealized gain (loss) on available for sale investments	8,000	(9,000)	-
Pension related, net of deferred taxes	34,000	120,000	(330,000)
Comprehensive loss	$ (4,288,000)	$ (4,479,000)	$ (3,509,000)

Accumulated other comprehensive loss at March 31, 2012 totaled $364,000 and consists of a $140,000 loss for accumulated translation adjustment, $1,000 for unrealized loss on available for sale investments and a $223,000 loss, net of deferred taxes of $56,000, for accumulated additional pension liability. Accumulated other comprehensive loss at March 31, 2011 totaled $327,000 and consisted of a $60,000 loss for accumulated translation adjustment, $9,000 for unrealized loss on available for sale investments and a $258,000 loss, net of deferred taxes of $18,000, for accumulated additional pension liability.

4. Commitments and Contingencies

Royalties. We received an absolute assignment of a patent relating to the Macroplastique Implantation System, in return for a royalty of 10 British Pounds for each unit sold during the life of the patent. Under the terms of an agreement with some former officers and directors of our company, we pay royalties equal to five percent of the net sales of certain Macroplastique products, subject to a specified monthly minimum of $4,500. The royalties payable under this agreement will continue until certain patents referenced in the agreement expire in 2013 and 2015. We recognized an aggregate of $383,000, $266,000 and $237,000 of royalty expense, under these agreements in fiscal

2012, 2011 and 2010, respectively.

Table of Contents

Purchase Requirements. In our normal course of business we have commitments, generally for periods of less than one year, to purchase from various vendors finished goods and manufacturing components under issued purchase orders. As of March 31, 2012 payments of our contractual obligations for purchase commitments within the next twelve months are $531,000.

Operating Lease Commitments. We lease office, warehouse, and production space under operating lease agreements, which include escalating lease payments, and lease various automobiles for our European employees. These leases expire at various times through April 2014. At March 31, 2012, the approximate future minimum lease payments in subsequent fiscal years under noncancelable operating leases with an initial term in excess of one year are as follows:

2013	$204,000
2014	187,000
2015	37,000
2016	10,000
	$438,000

Total operating lease expenses were $271,000, $249,000 and $250,000 in fiscal 2012, 2011and 2010, respectively.

Employment Agreements. We have entered into employment agreements with certain officers, the terms of which, among other things, specify a base salary subject to annual adjustments by mutual agreement of the parties, and a severance payment to the employee upon employment termination without cause. We provide for various severance amounts payable under the agreements after employment termination. Contemporaneously with the execution of their employment agreement, some of the officers executed an “Employee Confidentiality, Inventions, Non-Solicitation, and Non-Compete Agreement.” This agreement prohibits the employee from disclosing confidential information, requires the employee to assign to us without charge all intellectual property relating to our business which is created or conceived during the term of employment, prohibits the employee from encouraging employees to leave our employment for any reason and prohibits competition with us during the term of employment and for a specified term thereafter.

Product Liability. The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Any defects or risks that we have not yet identified with our products may give rise to product liability claims. Our existing $10 million of worldwide product liability insurance coverage may be inadequate to protect us from liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer.

5. Savings and Retirement Plans

We sponsor various plans for eligible employees in the United States, the United Kingdom (UK), and The Netherlands. Our retirement savings plan in the United States conforms to Section 401(k) of the Internal Revenue Code and participation is available to substantially all employees. We may also make discretionary contributions ratably to all eligible employees. We made discretionary contributions to the U.S. plan of $218,000, $52,000 and $105,000 for fiscal 2012, 2011 and 2010, respectively.

Our international subsidiaries in the UK and The Netherlands have defined benefit retirement plans for eligible employees. These plans provide benefits based on the employee’s years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. We froze the UK

subsidiary's defined benefit plan on December 31, 2004. On March 10, 2005, we established a defined contribution plan for the UK subsidiary. As of April 1, 2005 we closed The Netherlands subsidiary's defined benefit retirement plan for new employees and established a defined contribution plan for them. The total contribution expense associated with the defined contribution plans in The Netherlands and the United Kingdom was $12,000, $6,000 and $14,000 for fiscal 2012, 2011 and 2010, respectively. The increased expense in fiscal year 2012 is caused by an increase in the number of plan participants. The decreased expense in fiscal year 2011 is caused by a reduction in the rate of company contribution for new employees and by a reduction in the number of plan participants.

The amortization of actuarial gains or losses is included as a component of the annual expense for a year if, as of the beginning of the year, the cumulative net gain or loss exceeds 10% of the greater of the projected benefit obligation or plan assets. If amortization is required, the amortization is that excess divided by the expected average future service of the active employees participating in the plans or the average remaining life expectancies of inactive employees.

Table of Contents

The Netherlands defined benefit plan

The Netherlands defined benefit pension plan is funded through a guaranteed insurance contract with Swiss Life, an insurance company. Our contract with Swiss Life requires of us to make annual premium payments which are sufficient to satisfy the Vested Benefit Obligation (VBO). Swiss Life does not hold separate investment assets for our contract, but rather is obligated to provide the stream of future benefits for the annual premium payments we make. We calculate the market value of the pension plan assets, held in Swiss Life insured assets, as the stream, based on mortality, of the earned guaranteed benefit payments discounted at market interest rate. The benefit obligation is calculated based on the same assumptions as well. Accordingly, the impact on pension plan assets of a change in assumption for discount rate and mortality would equally offset the change in VBO.

At March 31, 2012 we project the following benefit payments in subsequent fiscal years:

2013	$-
2014	1,000
2015	4,000
2016	23,000
2017	24,000
2018 to 2022	146,000
	$198,000

We contributed $154,000 in fiscal 2012, $135,000 in fiscal 2011, $129,000 in fiscal 2010, and expect to contribute approximately $138,000 in fiscal 2013.

The following table summarizes the change in benefit obligations and the change in plan assets for the years ended March 31:

	2012	2011
Changes in benefit obligations:		
Projected benefit obligation, beginning of year	$1,427,000	$1,753,000
Service cost	73,000	95,000
Interest cost	86,000	81,000
Actuarial result	70,000	(560,000)
Foreign currency translation	(84,000)	58,000
Projected benefit obligation, end of year	$1,572,000	$1,427,000
Changes in plan assets:		
Plan assets, beginning of year	$1,041,000	$1,252,000
Contributions to plan	154,000	135,000
Management cost	(14,000)	(12,000)
Actual return on assets	100,000	(377,000)
Foreign currency translation	(64,000)	43,000
Plan assets, end of year	$1,217,000	$1,041,000

Table of Contents

The amount recognized in other comprehensive loss at March 31 consists of:

	2012	2011
Unrecognized net prior service benefit	$(357,000)	$(410,000)
Unrecognized net losses	411,000	501,000
Additional other comprehensive loss (gross of deferred taxes)	$ 54,000	$ 91,000

The projected benefit obligation, accumulated benefit obligations and the fair value plan assets at March 31 were as follows:

	2012	2011
Projected benefit obligation	$1,572,000	$1,427,000
Accumulated benefit obligation	1,253,000	1,075,000
Fair value of plan assets	1,217,000	1,041,000

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets on March 31, 2012 and 2011, of $355,000 and $386,000, respectively, as accrued pension liability.

The cost of our defined benefit retirement plan includes the following components for the years ended March 31:

	2012	2011	2010
Gross service cost, net of employee contribution	$58,000	$80,000	$45,000
Interest cost	86,000	81,000	67,000
Management cost	14,000	12,000	16,000
Expected return on assets	9,000	(24,000)	29,000
Amortization	(6,000)	5,000	-
Net periodic retirement cost	$161,000	$154,000	$157,000

Major assumptions used in the above calculations include:

	2012	2011
Discount rate	5.80 %	6.20 %
Expected return on assets	5.80 %	6.20 %
Expected rate of increase in future compensation:		
General	2.5 %	3.0 %
Individual	0-3 %	0-3 %

The discount rate used is based upon the yields available on high quality corporate bonds with a term that matches the liabilities. The impact of the decrease in discount rate used for March 31, 2012 over 2011 was an increase in the projected benefit obligation and actual return on assets.

The UK defined benefit plan

As of March 31, 2012 and 2011, we held all the assets of the U.K. defined benefit pension plan in a Deposit Administration Contract with Phoenix Life Limited.

At March 31, 2012 we project the following benefit payments in subsequent fiscal years:

2013	$-
2014	-
2015	-
2016	-
2017	87,000
2018 to 2022	128,000
	$215,000

Table of Contents

We contributed $35,000 in fiscal 2012, $36,000 in fiscal 2011, $39,000 in fiscal 2010, and expect to contribute approximately $35,000 in fiscal 2013.

The following table summarizes the change in benefit obligations and the change in plan assets for the years ended March 31:

	2012	2011
Changes in benefit obligations:		
Projected benefit obligation, beginning of year	$652,000	$577,000
Service cost	5,000	3,000
Interest cost	36,000	33,000
Other	(5,000)	(5,000)
Actuarial result	47,000	6,000
Foreign currency translation	(2,000)	38,000
Projected benefit obligation, end of year	$733,000	$652,000
Changes in plan assets:		
Plan assets, beginning of year	$562,000	$477,000
Contributions to plan	35,000	36,000
Management cost	(5,000)	(5,000)
Actual return on assets	23,000	22,000
Foreign currency translation	(1,000)	32,000
Plan assets, end of year	$614,000	$562,000

The amount recognized in other comprehensive loss at March 31 consists of:

	2012	2011
Unrecognized net losses (gross of deferred taxes)	$225,000	$185,000

The projected benefit obligation, accumulated benefit obligation and the fair value plan assets at March 31 were as follows:

	2012	2011
Projected benefit obligation	$733,000	$652,000
Accumulated benefit obligation	733,000	652,000
Fair value of plan assets	614,000	562,000

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets of $119,000 and $90,000, as of March 31, 2012 and March 31, 2011, respectively, as accrued pension liability.

The cost of our defined benefit retirement plan includes the following components for the years ended March 31:

	2012	2011	2010
Gross service cost, net of employee contribution	$5,000	$3,000	$3,000

Interest cost	36,000	33,000	25,000
Expected return on assets	(29,000)	(26,000)	(23,000)
Amortization	12,000	12,000	-
Net periodic retirement cost	$24,000	$22,000	$5,000

Table of Contents

Major assumptions used in the above calculations include:

	2012		2011	
Discount rate	4.90	%	5.50	%
Expected return on assets	3.40	%	5.00	%

The discount rate used is based upon the yields available on high quality corporate bonds with a term that matches the liabilities.

Plan Assets

The primary objective of the Netherlands pension plan is to meet retirement income commitments to plan participants at a reasonable cost. In The Netherlands, consistent with typical practice, the pension plan is funded through a guaranteed insurance contract with Swiss Life, an insurance company. Swiss Life is responsible for the investment strategy of the insurance premiums we make. We have characterized the assets of the pension plan as an "other contract."

The primary objective of the U.K. pension plan is to meet retirement income commitments to plan participants at a reasonable cost. The objective is achieved through growth of capital and safety of funds invested. The pension plan assets are invested in a Deposit Administration Contract with Phoenix Life Limited, an insurance company, with underlying investments primarily in fixed interest U.K. government bonds.

The allocation of pension plan assets as of March 31 was as follows:

	2012				2011			
	Target Allocation		Actual Allocation		Target Allocation		Actual Allocation	
Other Contract (Netherlands Plan)	100	%	100	%	100	%	100	%
Deposit Administration Contract (U.K. Plan)	100	%	100	%	100	%	100	%

We calculate the market value of the pension plan assets, held in Swiss Life insured assets, as the stream, based on mortality (an unobservable input), of the earned guaranteed benefit payments discounted at market interest rate. Accordingly, we have classified the Netherlands pension plan assets as Level 3 assets. The market value of the U.K. pension plan reflects the value of our contributions to the plan and the credited accrued interest at the rate specified in the Deposit Administration Contract. Accordingly, we have classified the U.K. plan assets as Level 2 assets.

The fair value of the pension plan assets at March 31 by asset class is as follows:

Asset Class	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

2012				
Other Contract (Netherlands Plan)	$ 1,217,000	$ -	$ -	$ 1,217,000
Deposit Administration Contract (U.K. Plan)	614,000	-	614,000	-
2011				
Other Contract (Netherlands Plan)	$ 1,041,000	$ -	$ -	$ 1,041,000
Deposit Administration Contract (U.K. Plan)	562,000	-	562,000	-

Table of Contents

The reconciliation of beginning and ending balances for our Level 3 assets is as follows:

	Other Contract (Netherlands Pension Plan Assets)
Beginning balance as at April 1, 2011	$ 1,041,000
Loss recognized in earnings	(23,000)
Unrealized actuarial gain recognized in other comprehensive loss	108,000
Purchases	154,000
Unrealized foreign currency translation loss recognized in other comprehensive loss	(63,000)
Ending balance as at March 31, 2012	$ 1,217,000

The unrealized actuarial gain of $108,000, recognized in other comprehensive loss, is equally offset by an unrealized actuarial loss, recognized in other comprehensive income, in the Vested Benefit Obligation.

6. Income Taxes

The components of income tax expense for the years ended March 31 consist of the following:

	2012	2011	2010
Income tax provision:			
Current:			
U.S. and State	$ 16,000	$ 3,000	$ 24,000
Foreign	35,000	33,000	24,000
Deferred:			
Foreign	(3,000)	(7,000)	(7,000)
Total income tax expense	$ 48,000	$ 29,000	$ 41,000

Actual income tax expense differs from statutory federal income tax benefit for the years ended March 31 as follows:

	2012	2011	2010
Statutory federal income tax benefit	$ (1,429,000)	$ (1,571,000)	$ (1,140,000)
State tax benefit, net of federal taxes	(91,000)	(113,000)	(88,000)
Foreign tax	(35,000)	(25,000)	(23,000)
Nondeductible expenses	75,000	50,000	-
Subpart F Income	35,000	43,000	-
Undistributed foreign earnings	9,000	137,000	-
Foreign tax credits	-	(33,000)	-
Valuation allowance increase	1,355,000	985,000	1,209,000
Expiration and adjustments of NOL’s	-	757,000	-
Other	129,000	(201,000)	83,000
Total income tax expense	$ 48,000	$ 29,000	$ 41,000

58

Table of Contents

Deferred taxes at March 31 consist of the following:

	2012	2011
Deferred tax assets (liabilities):		
Depreciation	$ (52,000)	$ (70,000)
Amortization	(175,000)	(468,000)
Pension liability	105,000	104,000
Stock based compensation	1,018,000	934,000
Other reserves and accruals	189,000	161,000
Undistributed foreign earnings	(302,000)	(293,000)
Foreign tax credits	68,000	148,000
Net operating losses	10,929,000	9,911,000
	$ 11,780,000	$ 10,427,000
Less valuation allowance	(11,657,000)	(10,340,000)
	$ 123,000	$ 87,000

At March 31, 2012, we had U.S. net operating loss (NOL) carryforwards of approximately $30 million for U.S. income tax purposes, which expire in 2012 through 2031, and NOLs in the U.K. of approximately $90,000, which we can carry forward indefinitely. U.S. NOL carryforwards cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of U.S. NOL carryforwards is subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. We believe that the issuance of our common stock in the December 2006 public offering resulted in an “ownership change” under Section 382. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 is limited to approximately $750,000 per year. We also believe that the issuance of our common stock in the July of 2010 public offering resulted in an additional "ownership change" under Section 382. Accordingly, our ability to use NOL tax attributes generated after December 2006 and prior to July 2010 is limited to approximately $2,350,000 per year.

Approximately $1.9 million of our NOL carryforwards resulted from the exercise of stock options. When these loss carryforwards are realized, the corresponding change in valuation allowance will be recorded as additional paid-in capital.

We provide for a valuation allowance when it is more likely than not that we will not realize a portion of the deferred tax assets. We have established a valuation allowance for all U.S. and certain foreign deferred tax assets due to the uncertainty that enough taxable income will be generated in those taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such deferred tax assets in the accompanying financial statements. The deferred tax asset increased by $1,353,000 and $963,000, respectively, in fiscal 2012 and 2011. The related valuation allowance increased by $1,317,000 and $985,000, respectively, in fiscal 2012 and 2011.

We have provided for U.S. deferred income taxes as of March 31, 2012 for the undistributed earnings from our non-U.S. subsidiaries.

7. Business Segment Information

ASC 280, “Segment Reporting,” establishes disclosure standards for segments of a company based on management’s approach to defining operating segments. In accordance with the objective and basic principles of the standard we

aggregate our operating segments into one reportable segment.

Information regarding geographic area sales to customers for the years ended March 31 is as follows:

	United States	United Kingdom	All Other Foreign Countries (1)	Consolidated
2012	$ 13,854,000	$ 1,929,000	$ 4,779,000	$ 20,562,000
2011	7,908,000	1,481,000	4,398,000	13,787,000
2010	6,056,000	1,578,000	4,229,000	11,863,000

(1) No country accounts for 10% or more of the consolidated sales

Table of Contents

Information regarding geographic area long-lived assets at March 31 is as follows:

	United States	United Kingdom	The Netherlands	Consolidated
2012	$ 509,000	$ 17,000	$ 646,000	$ 1,172,000
2011	506,000	2,000	702,000	1,210,000

Accounting policies of the operations in the various geographic areas are the same as those described in Note 1. Sales attributed to each geographic area are net of intercompany sales and are attributed to countries based on location of customers. No single customer represents 10% or more of our consolidated net sales. Long-lived assets consist of property and equipment.

8. Selected Consolidated Quarterly Data (Unaudited)

The following table presents selected unaudited consolidated financial data for each of the eight quarters in the two-year period ended March 31, 2012. In our opinion, this unaudited information is prepared on the same basis as the audited information and includes all adjustments (consisting of only normal recurring adjustments) necessary for a fair statement of the financial information for the period presented. The summation of quarterly data may not equate to the calculation for the full fiscal year as quarterly calculations are performed on a discrete basis.

	2012				
	Q1	Q2	Q3	Q4	Annual
Net Sales	$4,653,000	$4,968,000	$5,344,000	$5,597,000	$20,562,000
Gross Profit	3,944,000	4,208,000	4,568,000	4,805,000	17,525,000
Net Loss	(1,331,000)	(1,278,000)	(1,068,000)	(573,000)	(4,250,000)
Basic and Diluted Loss per Share	$(0.06)	$(0.06)	$(0.05)	$(0.03)	$(0.21)

	2011				
	Q1	Q2	Q3	Q4	Annual
Net Sales	$3,035,000	$3,245,000	$3,492,000	$4,015,000	$13,787,000
Gross Profit	2,525,000	2,650,000	2,888,000	3,338,000	11,401,000
Net Loss	(929,000)	(923,000)	(1,468,000)	(1,328,000)	4,648,000
Basic and Diluted Loss per Share	$(0.06)	$(0.05)	$(0.07)	$(0.06)	$(0.25)