UROPLASTY INC
Form 10-K
May 25, 2011

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, 2011

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 ¨ NO T

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 ¨ NO T

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 T NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 ¨ NO ¨

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. T

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 T	Non-Accelerated Filer ¨	Smaller Reporting Company T

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
YES ¨ NO T

The aggregate market value of the voting stock held by non-affiliates computed by reference to the price at which the stock was sold or the average bid and asked prices of such stock as of March 31, 2011 was $131,551,817.

As of May 24, 2011 the registrant had 20,664,332 shares of common stock outstanding.

Documents Incorporated By Reference: Portions of our Proxy Statement for our 2010 Annual Meeting of Shareholders (the "Proxy Statement"), are incorporated by reference in Part III.

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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.

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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. 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 the associated symptoms of urinary urgency, urinary frequency, and urge incontinence; and Macroplastique®, 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, fecal incontinence 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 tibial nerve stimulation (PTNS) to deliver to the tibial nerve an electrical pulse that travels 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 the patient 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 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 sponsored several clinical studies, and supported by publication of clinical studies in U.S. peer-reviewed journals, we applied for, and the AMA granted, a listed Category I CPT code for PTNS treatments, which became effective in January 2011, the fourth quarter of our fiscal 2011. The AMA advised us of this decision prior to the effective date and we began to expand our sales organization in anticipation of increased reimbursement coverage.

In order for our business to grow, we will need to continue to expand third-party reimbursement coverage for PTNS treatments. Our initial focus for expanding reimbursement coverage has been on Medicare carriers, but we also continue to target selected private-payers. Accordingly, to help us secure broader reimbursement coverage, we have instituted a comprehensive program designed to educate Medicare carriers and private payer medical directors about the clinical effectiveness, cost effectiveness and patient benefits of PTNS treatments using our Urgent PC System.

To date, ten regional Medicare carriers representing 35 states, with approximately 31 million covered lives, have indicated they will provide coverage for PTNS treatments. Three regional Medicare carriers representing 15 states, with approximately 16 million covered lives, continue to decline reimbursement coverage for PTNS treatments. We continue to work to have the decision to deny coverage reversed. Along with key opinion leaders from the urology field, we have met with the Medical Directors of these carriers to present additional data that we believe justifies a change in their coverage decision and, if need be, we will initiate a formal appeal process to have their decision reconsidered.

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In addition, we estimate that to date private payers providing insurance to approximately 70 million lives have elected to provide coverage for PTNS treatments. We are working with the Medical Directors of a number of other private payers to provide coverage for PTNS treatments.

In anticipation of increased interest in our Urgent PC System, we 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 31 employed sales representatives and two independent manufacturer's representatives on March 31, 2011. Our employed sales representatives generated approximately 95% of our U.S. sales in the fourth quarter of fiscal 2011 and 87% in fiscal 2011. We expect our employed sales representatives to generate a greater portion of our sales in the future.

We expect to further expand our U.S. field sales organization in the future. 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.

To assist with the funding of these increased sales expenses and working capital, we completed a public offering of 4.6 million shares of our common stock at price of $3.50 per share in July 2010, generating gross proceeds of $16.1 million, and net proceeds, after fees and expenses, of approximately $14.9 million.

Our net loss in fiscal 2011 increased primarily because of the increased spending for our expanded sales and marketing organization.

Market

Neuromodulation Market

Neuromodulation, a form of therapy in which a low-voltage electrical current is used 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.

Voiding Dysfunction Market

Voiding dysfunctions affect urinary or bowel control and can result in uncontrolled bladder sensations (overactive bladder) or unwanted leakage (urinary or 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 these 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 80% of the patients who discontinue drugs within one year due to poor efficacy or intolerance of side effects.

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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:

- Τεχηνολογψ αδϖανχεσ ανδ πατιεντ αωαρενεσσ. Πατιεντσ οφτεν ωειγη τηε χλινιχαλ βενεφιτσ, αδϖερσε σιδε εφφεχτσ ανδ τηε λεϖελ οφ ινϖασιϖενεσσ οφ τηε προχεδυρεσ, αλονγ ωιτη οτηερ φαχτορσ, ιν χηοοσινγ α τρεατμεντ αλτερνατιϖε. Ιν ρεχεντ ψεαρσ, ωιτη τηε πυβλιχιτψ ασσοχιατεδ ωιτη νεω τεχηνολογψ ανδ μινιμαλλψ ινϖασιϖε τρεατμεντ αλτερνατιϖεσ, ωε βελιεϖε τηε νυμβερ οφ πατιεντσ ϖισιτινγ πηψσιχιανσ το σεεκ τρεατμεντ φορ ϖοιδινγ δψσφυνχτιονσ ηασ ινχρεασεδ. Ασ α ρεσυλτ, ωε βελιεϖε μορε πατιεντσ ωιλλ χηοοσε το αϖοιδ δρυγ τηεραπψ ορ, βεχαυσε οφ αδϖερσε σιδε εφφεχτσ, χηοοσε το δισχοντινυε δρυγ τηεραπψ φορ οτηερ αλτερνατιϖεσ ωηιχη μορε σιμπλψ ανδ εφφεχτιϖελψ μαναγε τηειρ δισορδερ.

- 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.

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 non-surgical PTNS procedure.

- 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 because it is a non-surgical treatment.

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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 to the tibial nerve an electrical pulse that travels to the sacral nerve plexus, a control center for pelvic floor and bladder function.

We believe that the Urgent PC System is the only 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. 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.

Types of Urinary Incontinence

There are four types of urinary incontinence:

- Stress Urinary Incontinence — Stress urinary incontinence, or 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 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.
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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.

- 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.

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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. Hence, these materials are often called "bulking agents" or "injectables" and are an attractive alternative to surgery because they are considerably less invasive 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, stress urinary incontinence 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 stress incontinence due to ISD. We began marketing Macroplastique in the United States in early 2007.

Other Uroplasty Products

We also market outside of the U.S. minimally invasive products to address fecal 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 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 for patients who suffer from voiding dysfunctions. We believe that with our Urgent PC 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. We also believe that the availability of a listed CPT code for PTNS treatments will encourage broader use of our Urgent PC.

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- Educate physicians about the superior performance of Macroplastique. Although Macroplastique has been used in 40 countries outside of the U.S. for over two decades, it is not yet well known in the U.S. because it was only introduced for sale in 2007. However, sales in the U.S. have grown over the last two years as we have expanded our marketing activities and conducted specific sales training programs with our representatives to increase their ability to understand and advise clinicians as to its use and benefits. We believe Macroplastique is superior to other commercially available bulking agents because, with its unique composition, and soft-textured implant shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

- 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 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.

- 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.

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 25% and 28% of our total net sales for fiscal 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 technical 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.

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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 listed Category I CPT code for PTNS treatments has encouraged, and will continue to encourage, broader use of our Urgent PC System. To date, ten regional Medicare carriers representing 35 states, with approximately 31 million covered lives, have indicated they will provide coverage for PTNS treatments. Three regional Medicare carriers representing 15 states, with approximately 16 million covered lives, continue to decline reimbursement coverage for PTNS treatments. We continue to work to have the decision to deny coverage reversed. Along with key opinion leaders in the urology field, we have met with the Medical Directors of these carriers to present additional data that we believe justifies a change in their coverage decision, and, if need be, we will initiate a formal appeal process to have their decision reconsidered.

In addition, we estimate that to date private payers providing insurance to approximately 70 million lives have elected to provide coverage for PTNS treatments. We are working with the Medical Directors of a number of other private payers to provide coverage for PTNS treatments.

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 (HEPA) 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.

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, tissue bulking agents 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.

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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 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 surgical intervention. Other companies may also enter the U.S. market with neuromodulation products for the treatment of OAB.

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); 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.

Soft-tissue injectable urethral bulking agents for SUI competing directly with Macroplastique in the United States include: Contigen® distributed by C.R. Bard, Inc.; Durasphere® manufactured by Carbon Medical Technologies and distributed by Coloplast; and Coaptite® manufactured by BioForm, Inc. and distributed by Boston Scientific. We understand C.R. Bard, Inc. will discontinue distributing Contigen sometime by mid-calendar year 2011. We believe Macroplastique competes favorably against these products because it will not degrade, resorb or migrate, has no special preparation or storage requirements, is safe and effective, and does not require the patient to have a skin allergy test prior to the procedure.

Outside of the United States, Deflux® (manufactured by Q-Med AB, Sweden) and Bulkamid® (manufactured by Contura, Denmark) 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.

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.

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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.

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.

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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 neurostimulation product, “Macroplastique” for our urological tissue bulking products, “VOX” for our otolaryngology tissue bulking products, “PTQ” for our colorectal tissue bulking products, and “Bioplastique” for soft 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 $1.7 million and $1.8 million for fiscal 2011 and 2010, respectively.

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

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Backlog

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

Employees

As of March 31, 2011, we had 88 employees, of which 83 were full-time and 5 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 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:

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, 2011, we had an accumulated deficit of approximately $31 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.

We are dependent on the availability of third-party reimbursement for our revenues.

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. 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.

In the United States, while we believe the availability, effective January 2011, of a listed CPT code for PTNS treatments will encourage broader use of our Urgent PC Neuromodulation System, there is 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 be challenged (as it was in fiscal 2009) in a manner that causes payers to reverse coverage decisions, or that government actions will not decrease the level of reimbursement.

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In international markets, market acceptance of our products also depends in part upon the availability of reimbursement from healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. The main types of healthcare payment systems in international markets are government-sponsored healthcare and private insurance. Countries with government-sponsored healthcare, such as the United Kingdom, have a centralized, nationalized healthcare system. New devices are brought into the system through negotiations between departments at individual hospitals at the time of budgeting. In many of the countries where we market our products, the government sets an upper limit of reimbursement for various treatment procedures. In most foreign countries, there are also private insurance systems that may offer payments for alternative procedures.

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.

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, and to train physicians in the proper application of our products. We cannot assure you that we will be successful in educating the marketplace about the benefits of our products. Even if customers accept our products, this acceptance may not translate into sales if our competitors have developed similar products that our customers prefer.

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 renewed 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.

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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.

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 2011, sales of our Urgent PC System and Macroplastique accounted for approximately 40% 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 a substantial 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.

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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.

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 a 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.

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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.

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.

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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.

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 43% of our sales in fiscal 2011 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.

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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;
- 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, 2011, we have 2,066,000 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.

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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.

Item 3. Legal Proceedings

We are not currently subject to any material pending legal proceedings.

Item 4. Reserved

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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 Markets 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, 2011 and 2010 as reported on the NYSE AMEX and, effective July 12, 2010, the NASDAQ Capital Markets.

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, 2011, we had approximately 475 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, 2011.

	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)	1,166,000	$ 2.89	1,305,000

Equity Compensation Plans Not Approved by Security Holders (2)	900,000	$	4.05	-
Total	2,066,000	$	3.39	1,305,000

(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.

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Item 6. Selected Financial Data

Not applicable

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®, 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 sponsored several clinical studies, and supported by publication of clinical studies in U.S. peer-reviewed journals, we applied for, and the AMA granted, a listed Category I CPT code for PTNS treatments, which became effective in January 2011, our fourth fiscal quarter of 2011. The AMA advised us of this decision prior to the effective date and we began to expand our sales organization in anticipation of increased reimbursement coverage.

To date, ten regional Medicare carriers representing 35 states, with approximately 31 million covered lives, have indicated they will provide coverage for PTNS treatments. Three regional Medicare carriers representing 15 states, with approximately 16 million covered lives, continue to decline reimbursement coverage for PTNS treatments. We continue to work to have the decision to deny coverage reversed. In addition, we estimate that to date private payers providing insurance to approximately 70 million lives have elected to provide coverage for PTNS treatments. We are working with the Medical Directors of a number of other private payers to provide coverage for PTNS treatments.

In anticipation of increased interest in our Urgent PC System with the assignment of the new CPT code for PTNS treatments, we have expanded our U.S. field sales and support organization. On April 1, 2010 we had 15 employed sales representatives and six independent manufacturer's representatives, and by March 31, 2011, we had 31 employed sales representatives and two independent manufacturer's representatives. Our employed sales representatives

generated approximately 95% of our U.S. sales in the fourth quarter of fiscal 2011 and 87% in fiscal 2011. We expect our employed sales representatives to generate a greater portion of our sales in the future.

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 sales. 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 two 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.

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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 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 2011 or 2010.

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, 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 accounting rules, changes in benefit obligations associated with these factors may not be immediately recognized as costs on the income statement, but are recognized in future

years over the remaining average service period of plan participants. See Note 5 to our consolidated financial statements for further discussion.

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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, 2011, we have generated approximately $27 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 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 issuance of our public offering of common stock in the 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 are limited.

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

Results of Operations

Net Sales. In fiscal 2011, net sales were $13.8 million, representing a $1.9 million or 16% increase compared to net sales of $11.9 million in fiscal 2010. Excluding the translation impact of fluctuations in foreign currency exchange rates, net sales increased by approximately 19%.

Sales to customers in the U.S. in fiscal 2011 totaled $7.9 million, representing a $1.8 million or 31% increase compared to $6.1 million in fiscal 2010.

Sales in the U.S. of our Urgent PC System increased 11% to $4.3 million in fiscal 2011, from $3.8 million in fiscal 2010. Sales of our Urgent PC System declined from a peak of $2.2 million in the first quarter of our fiscal 2009 to approximately $0.9 million to $1 million per quarter in the six subsequent quarters ended December 2010 because of the reimbursement-related issues noted previously.

In the fourth quarter ended March 31, 2011, Urgent PC sales in the U.S. were $1.3 million. We sold 1,668 Urgent PC lead set boxes to 346 customers in the fourth quarter ended March 31, 2011 compared to 1,379 boxes to 236 customers in the third quarter ended December 31, 2010. We believe the increase in sequential sales of lead set boxes and number of customers in the fourth quarter is attributed primarily to the listed CPT code assigned effective January 2011 and expanded third-party coverage for PTNS treatments. While we expect the number of customers to continue to increase, we believe the large sequential increase in the fourth quarter ended March 31, 2011 is partially attributed to the pent up demand for our product.

Sales in the U.S. of our Macroplastique product increased 60% to $3.5 million in fiscal 2011, from $2.2 million in fiscal 2010. Sales of our Macroplastique product increased as a result of our increased sales and marketing focus on this product.

Sales to customers outside the U.S. increased 1% to $5.9 million in fiscal 2011, from $5.8 million in fiscal 2010. Excluding the translation impact of fluctuations in foreign currency exchange rates, sales increased by approximately 7%.

Gross Profit: Gross profit was $11.4 million in fiscal 2011 and $9.8 million in fiscal 2010, or 83% of net sales in both years. In fiscal 2011, we had a favorable impact of increase in manufacturing capacity utilization 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 $3.4 million 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, 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 decreased to $1.7 million in fiscal 2011, from $1.8 million in fiscal 2010. Included in fiscal 2011 is a $27,000 charge for non-cash, share-based compensation expense, compared with $49,000 in fiscal 2010. Excluding share-based compensation charges, R&D expenses decreased by $43,000. 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.

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Selling and Marketing Expenses (S&M): 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. As the result of the increased interest in our Urgent PC after the new CPT code became effective, we expanded our U.S. field sales and support organization in our third quarter. Accordingly, we incurred increased S&M expenses during the third and fourth quarters.

Amortization of Intangibles: Amortization of intangibles was $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.

Other Income (Expense): Other income (expense) includes interest income, interest expense, foreign currency exchange gains and losses and other non-operating costs when incurred. Net other income was $77,000 and $40,000 for fiscal years 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. We recognized foreign currency exchange gain of $11,000 in fiscal 2011 and foreign currency exchange loss of $38,000 in fiscal 2010.

Income Tax Expense: In fiscal 2011 and fiscal 2010, we recorded income tax expense of $29,000 and $41,000, respectively. 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 2011 and 2010 was approximately $3.1 million and $1.7 million, respectively.

		Expense Adjustments		
	GAAP	Share-based Compensation	Depreciation	Amortization	Non-GAAP

Year Ended March 31, 2011					
Gross Profit	$11,401,000	$17,000	$ 52,000		$11,470,000
% of sales	83 %				83 %
Operating Expenses					
General & administrative	3,442,000	(269,000)	(150,000)		3,023,000
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)	-
	16,098,000	(417,000)	(223,000)	(844,000)	14,614,000
Operating Loss	$(4,697,000)	$434,000	$ 275,000	$ 844,000	$(3,144,000)
Year Ended March 31, 2010					
Gross Profit	$9,805,000	$27,000	$ 58,000		$9,890,000
% of sales	83 %				83 %
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)	(66,000)		7,364,000
Amortization	846,000			$ (846,000)	-
	13,007,000	(387,000)	(234,000)	(846,000)	11,540,000
Operating Loss	$(3,202,000)	$414,000	$ 292,000	$ 846,000	$(1,650,000)

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Liquidity and Capital Resources

Cash Flows.

At March 31, 2011, we have total cash and investments of $19.6 million, which includes $14.1 million of cash, cash equivalents and short-term investments and $5.5 million of long-term investments.

At March 31, 2011, we had working capital of approximately $14.7 million. In fiscal 2011, we used $3.4 million of cash in operating activities, compared to $1.9 million of cash used in fiscal 2010. We attribute the increase in cash used in operating activities primarily to the increase of $1.5 million in the operating loss, an increase in inventories and receivables due to the increase in sales, offset partially by an increase in accrued liabilities, primarily related to accruals of compensation-related expenses.

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

In fiscal 2011 we generated proceeds from financing activities of approximately $17.5 million, consisting of approximately $14.9 million in net proceeds from the public offering of our common stock and approximately $2.5 million from the exercise of warrants and options. In July 2010, in a public offering of our common stock, we issued 4.6 million shares (inclusive of the over-allotment exercised by the underwriters) at a price of $3.50 per share, for gross proceeds of $16.1 million, and net proceeds, after fees and expenses, of approximately $14.9 million. We anticipate using the proceeds to expand our U.S. sales and marketing organization to support our Urgent PC business and for clinical studies, working capital and general corporate purposes. As a result of increased interest in our Urgent PC after the new CPT code became effective, we expanded our U.S. field sales and support organization.

Sources of Liquidity.

Uroplasty BV, our subsidiary, has an agreement with Rabobank of The Netherlands for a €500,000 (approximately $705,000) 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% base rate on March 31, 2011), subject to a minimum interest rate of 3.50% per annum. We had no borrowings outstanding on this credit line at 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 broad reimbursement for our Urgent PC product and successfully demonstrating the superiority of our Macroplastique product to clinicians. We cannot guarantee that we will be entirely successful in either of these pursuits. 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.

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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.

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 British pounds for each unit sold during the life of the patent.

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.

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, 2011, and fiscal 2012 pension expense to the following changes in key assumptions:

Assumption:	Increase/(Decrease) Funded Status at March 31, 2011	Increase/(Decrease) Fiscal 2012 pension expense
Increase in discount rate by 1 percentage point	$ 221,000	$ (23,000)
Decrease in discount rate by 1percentage point	(295,000)	29,000
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	(291,000)	53,000
Decrease in inflation rate by 1 percentage point	243,000	(44,000)
Increase in compensation increase by 1 percentage point	(209,000)	43,000
Decrease in compensation increase by 1 percentage point	6,000	(1,000)

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 $89,000 over 12 months.

Recent Accounting Pronouncements

In January 2010, the Financial Accounting Standards Board issued Accounting Standards Update (ASU) No. 2010-06, "Fair Value Measurements and Disclosures: Improving Disclosures about Fair Value Measurements" (ASU 2010-06). This update provides amendments to ASC 820-10 that requires new disclosures and clarifies existing disclosures. Part of the ASU was effective for the fourth quarter of our fiscal 2010. The adoption did not have an impact on our financial position or results of operations. The disclosures about purchase, sales, issuances, and settlements in the roll forward of activity in level 3 fair value measurements became effective starting the fourth quarter of our fiscal 2011. The adoption did not have an impact on our financial position or results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not Applicable

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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, 2011.

The effectiveness of our internal control over financial reporting as of March 31, 2011, 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, 2011, 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, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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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.

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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, 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)
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)*

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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)
	* Management contract, compensation plan or arrangement

(c) Exhibits filed herewith.

Number	Description
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 25, 2011

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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 25, 2011

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 25, 2011
/s/ Mahedi A. Jiwani Mahedi A. Jiwani	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	May 25, 2011
/s/ R. Patrick Maxwell* R. Patrick Maxwell	Chairman of the Board of Directors	May 25, 2011
/s/ Thomas E. Jamison* Thomas E. Jamison	Director	May 25, 2011
/s/ Lee A. Jones* Lee A. Jones	Director	May 25, 2011
/s/ Robert C. Kill* Robert Kill	Director	May 25, 2011
/s/ James P. Stauner* James P. Stauner	Director	May 25, 2011
/s/ Sven A. Wehrwein* Sven A. Wehrwein	Director	May 25, 2011

*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.