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**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, 2010**

**Commission File No. 001-32632**

**UROPLASTY, INC.**

(Exact name of registrant as specified in its Charter)

**Minnesota**  
(State or other jurisdiction of  
incorporation or organization)

**41-1719250**  
(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:

<u>Title of class</u>	<u>Name of Exchange on which registered</u>
Common Stock, \$.01 par value	NYSE AMEX

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES [X] NO [ ]

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. [X]

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

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

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

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 May 21, 2010 was \$74,037,000.

As of May 21, 2010 the registrant had 15,310,040 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

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This Form 10-K contains “forward-looking statements” relating to projections, plans, objectives, estimates, and other statements of future economic 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, or 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 is subject to changes in general economic conditions, competition, reimbursement levels, customer and market preferences, government regulation, the impact of tax regulation, foreign exchange rate fluctuations, the degree of market acceptance of products, the uncertainties of potential litigation, as well as other risks and uncertainties detailed elsewhere in this report. By their very nature, forward-looking statements are subject to known and unknown risks and uncertainties relating to our future performance that may cause our actual results, performance or achievements, or industry results, to differ materially from those expressed or implied in any such forward-looking statements.

Forward-looking statements are contained in the “Management’s Discussion and Analysis or Plan of Operation” and other sections of this report. Various factors and risks (not all of which are identifiable at this time) could cause our results, performance or achievements to differ materially from that contained in our forward-looking statements. We caution investors that any forward-looking statement contained herein or elsewhere is qualified by and subject to the warnings and cautionary statements contained above and in this report and, in particular, in the “Risk Factors” discussion contained in Item IA of this report.

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

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PART I

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**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<sup>®</sup> system, which we believe is the only FDA-approved minimally invasive, office-based neuromodulation therapy for the treatment of urinary urgency, urinary frequency, and urge incontinence — symptoms often associated with overactive bladder (OAB); and Macroplastique<sup>®</sup>, 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 is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence and vesicoureteral reflux.

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

The Urgent PC system uses percutaneous tibial nerve stimulation (PTNS) to deliver 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 neurostimulation 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, 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 growth during fiscal 2007 and 2008 was largely attributable to rapid market acceptance of our Urgent PC product in the U.S. However, our sales performance in the U.S. was impacted by the American Medical Association's (AMA) advice to the medical community, during our first fiscal quarter of 2009, that the previously recommended unique, listed CPT code for Urgent PC treatments be replaced with an unlisted code. As a result, some third-party insurance carriers are delaying or denying reimbursement while certain other insurer are reassessing their coverage and reimbursement policies for Urgent PC treatments. However, many other third party payers, under a published positive coverage policy or on a case-by-case basis, continue to provide reimbursement for Urgent PC treatments.

Starting in the second half of fiscal 2009, sales over corresponding year-ago periods of our Urgent PC system declined and continued to do so in fiscal 2010 because of reimbursement-related issues, although sales stabilized at around \$0.9 million to \$1 million per quarter in fiscal 2010. We expect Urgent PC sales in the U.S. will likely decline further in fiscal 2011 and we do not expect the sales to return to prior historical levels until after we obtain a unique, listed CPT code and payers create coverage policies that provide adequate reimbursement.

A major part of our strategy, supported by publication of clinical studies in peer-reviewed journals in the U.S., has been to obtain a unique, listed Current Procedure Technology (CPT) code for PTNS, and expand third-

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party reimbursement coverage of Urgent PC treatments in the U.S. Additionally, we continue to implement a comprehensive program designed to educate Medicare carriers and private payer medical directors about the benefits and clinical study results of Urgent PC. During the past eighteen months we have sponsored and received favorable results from clinical trials designed to demonstrate the efficacy of our Urgent PC system, and to date five new articles have been published in U.S. medical journals on Urgent PC. The most recent publications in *The Journal of Urology*<sup>®</sup> include the results of the 12-week OrBIT clinical trial, published in the September 2009 issue, the long-term phase of the OrBIT clinical trial, published in the January 2010 issue, and the 12-week SUmIT clinical trial, published in the April 2010 issue.

We submitted an application for a unique, listed CPT code to the AMA, for consideration at their CPT Editorial Panel Meeting in February 2010. The AMA has advised us that they have assigned a unique, listed CPT code for PTNS. This decision is expected to be published in the Federal Register by the Centers for Medicare and Medicaid Services by October 2010. Nevertheless, the code will not become effective until January 2011, the suggested reimbursement amount for Urgent PC treatments is not yet established, the exact CPT code number is not yet assigned, and no private payers or governmental agencies have agreed, or considered to agree, to provide reimbursement on the basis of this new CPT code prior to its effective date. While we believe the availability of a unique, listed CPT code will encourage broader use of our Urgent PC, there is no assurance that additional payers will agree to create coverage policies or that the policies, if they create, will provide adequate reimbursement.

We have increased our emphasis on sales of our Macroplastique product in the United States. We have expanded our marketing activities and conducted specific sales training programs with our U.S. sales representatives to increase their ability to understand and advise clinicians as to its use and benefits with the expectation of increased sales. As a result, fiscal 2010 Macroplastique sales in the U.S. about doubled over fiscal 2009 and we anticipate increased sales in fiscal 2011.

Our net loss in fiscal 2010 decreased because of a decline in sales and a decline in gross margin, primarily because of lower capacity utilization, offset partially by a reduction in operating expenses. Our spending for R&D has declined as we complete clinical trials we undertook, primarily to support our Urgent PC business, and although we have maintained our assembled U.S. sales force and redirected some of their effort to our Macroplastique product line until reimbursement for Urgent PC stabilizes, we have taken steps to control our other sales and marketing spending.

## Market

### *Neurostimulation Market*

Neurostimulation, 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-approved neurostimulation 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 different parts of the nervous system, including the spinal cord, sacral nerves and vagus nerve, among other areas. We believe the neurostimulation market represents a significant opportunity for us in the treatment of urinary symptoms often associated with OAB.

### *Voiding Dysfunction Market*

Voiding dysfunctions affect urinary or fecal control and can result in uncontrolled bladder sensations (overactive bladder) or unwanted leakage (urinary or fecal incontinence). OAB is a prevalent and challenging urologic problem affecting an estimated 34 million adult Americans. In 1996, the Agency for Health Care Policy and Research (AHCPR), a division of the Public Health Service, U.S. Department of Health and Human Services, estimated that urinary incontinence affected about 13 million people in the United States, 85% (11 million) of whom were women. AHCPR estimated the total cost of treating incontinence (management and curative approaches) of all types in the United States at approximately \$16 billion per year. Historically, we believe only a small percentage of the patients suffering from these disorders have sought treatment. In

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recent years, however, we believe the number of people seeking treatment has grown as a result of the publicity associated with new, minimally invasive treatment alternatives.

When patients seek treatment, physicians generally assess the severity of the symptoms as mild, moderate or severe. However, regardless of the degree of severity, patients will often consider drug therapy and minimally invasive treatment first. We believe that we are uniquely positioned because we offer office-based, minimally invasive treatment solutions.

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 urinary symptoms often associated with OAB and urinary incontinence. These factors include the following:

- *Technology advances and patient awareness.* Patients often weigh the clinical benefits against the invasiveness of the procedures when choosing a treatment alternative. In recent years, with the publicity associated with new technology and minimally invasive treatment alternatives, we believe the number of patients visiting physicians to seek treatment for voiding dysfunctions has increased. As a result, we believe more patients will choose treatments other than drug therapy, which may have adverse side effects and may not achieve the desired therapeutic effect, or other alternatives, which simply manage their disorder.
- *Emphasis on quality of life.* Patients have placed an increased emphasis on quality of life issues and maintaining active lifestyles. Their desire to improve 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 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 neurostimulation.
- *Aging population.* The number of individuals developing voiding dysfunctions will increase as the population ages and as life expectancies continue to 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 an overactive bladder may seek to void over 20 times per day and at least 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 the restroom.

### Treatment of Symptoms

*Drug Therapy.* The most common treatment for OAB is drug therapy using an anticholinergic agent. However, for some individuals, the drugs are ineffective or the side effects so bothersome that the patient discontinues the medications. Common side effects include dry mouth, constipation, cognitive changes and blurred vision.

*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 and compliance of the individual. In addition, these techniques may not affect the underlying cause of the condition.

*Neurostimulation.* 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

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sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to OAB symptoms. Therapy using neurostimulation 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. Neurostimulation for urinary symptoms often associated with OAB is presently conducted through a surgically implanted sacral nerve stimulation device or non-surgical PTNS performed in a physician’s office.

- *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 that most office-based physicians will first recommend to patients drug therapy or PTNS treatments over the more invasive, surgically implanted procedure. We believe that patients may be more inclined to elect a less invasive treatment option for urinary symptoms instead of an invasive surgery.
- *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. Neurostimulation using PTNS has a therapeutic effect documented in published clinical studies. Because PTNS is non-surgical, it has a low risk of complication and is typically performed in a physician’s office.

## Uroplasty Solution

### *Urgent PC Non-Surgical Neurostimulation System*

The Urgent PC system is a minimally invasive nerve stimulation device designed for office-based treatment of urge incontinence, urinary urgency and urinary frequency — symptoms often associated with OAB. Using a small-gauge needle electrode inserted near the ankle, the Urgent PC system delivers an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function.

We believe that the Urgent PC system is the only PTNS device in the United States market for treatment of urinary symptoms often associated with OAB. Components of the Urgent PC 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 in the patient’s lower leg and connects the electrode to the stimulator. Typically, a patient undergoes 12 consecutive weekly treatment sessions, with follow-up maintenance treatments as required 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 complicated 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.

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### *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 intrinsic sphincter deficiency, or the inability of the sphincter valve or muscle to function properly. Intrinsic sphincter deficiency, or ISD, can be due to congenital sphincter weakness or can result from deterioration of the urethral muscular wall due to aging or damage following trauma, spinal cord lesion or radiation therapy.
- *Urge Incontinence* — Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate. Urge incontinence often occurs when neurologic problems cause the bladder to contract and empty with little or no warning.
- *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. We believe that patients prefer less invasive treatments that provide the most benefit and have little or no side effects.

### *Treatment*

*Injectable Bulking Agents.* Urethral bulking agents (UBAs) are injected into the area around the urethra, augmenting the surrounding tissue for increased capacity to control the release of urine. Hence, these materials are often called “bulking agents” or “injectables.” UBAs may be either synthetic or biologically derived and are an attractive alternative to surgery because they are considerably less invasive and do not require 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 help resolve lingering symptoms for patients who have undergone certain more invasive treatments, such as slings, which failed to completely resolve the stress urinary incontinence conditions.

*Surgery.* In women, stress urinary incontinence can be corrected through surgery with a 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

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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. The PTQ Implants are implanted circumferentially into the submucosa of the anal canal, creating a “bulking” and supportive effect similar to that of Macroplastique injection for the treatment of stress urinary incontinence. The 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 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:

- *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-part carriers. To this end, we have conducted clinical studies which we believe will help us with our sales and marketing efforts. We have also submitted the results of these clinical studies with our February 2010 application to the AMA for a unique, listed CPT code. We believe the availability of a unique, listed CPT code will encourage broader use of our Urgent PC.
- *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. are beginning to accumulate 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, 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 these 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.

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- *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 overactive bladder and incontinence symptoms. 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.
- *Increase market coverage in the United States.* We believe that in addition to the international markets where we have had a presence for many years, 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.
- *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 various preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. An important part of our growth strategy is to broaden our product line 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 of direct field sales personnel and independent sales representatives, 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 28% and 27% of our total net sales for fiscal 2010 and 2009, respectively.

We use clinical studies and 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 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 evaluation study design, abstract preparation, manuscript creation and review and submission.

### 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.

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As a relatively new therapy, PTNS using the Urgent PC system has not been assigned a reimbursement code unique to the technology. Currently, many third party payers, under a published positive coverage policy or on a case-by-case basis, provide reimbursement for Urgent PC treatments. However, to garner broader use, we believe Urgent PC treatments will need a unique, listed CPT code and for payers to create coverage policies that provide adequate reimbursement. We submitted an application to the AMA for a unique, listed CPT code for consideration at their February 2010 meeting. We have been advised that the AMA has determined to accept our request to assign a unique, listed CPT code for PTNS. This decision is expected to be published in the Federal Register by Centers for Medicare and Medicaid Services by October 2010 and becomes effective in January 2011. We believe the availability of a unique, listed CPT code will encourage broader use of our Urgent PC. We are also working with third-party payers for coverage policies, as well as educating medical directors, customers and patient advocates to secure broader acceptance of this therapy.

We believe there are appropriate CPT codes available to describe use of Macroplastique to treat adult female SUI due to ISD in the United States. We will need to foster coverage policies and payer acceptance to increasingly support sales 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 been able to get budgets approved by fund-holder trusts or global hospital budgets.

### **Manufacturing and Suppliers**

We have a U.S. Food and Drug Administration (FDA)-qualified manufacturing facility in Minnetonka, Minnesota. We subcontract the manufacturing of the Urgent PC system and its related components.

We manufacture all of our tissue bulking products at our Minnesota facility. 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 neurostimulation 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

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will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors affecting our success include our product development and innovation capabilities, clinical study results, ability to obtain required regulatory approvals, ability to protect our proprietary technology, manufacturing and marketing capabilities and ability to attract and retain skilled employees.

We believe, the Urgent PC neurostimulation system offers a minimally invasive, office-based treatment alternative to the more invasive implantable Medtronic InterStim<sup>®</sup> device. The Urgent PC is another alternative in the continuum of care for patients with urinary symptoms often associated with OAB. 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 system allows minimally invasive stimulation of the sacral nerve plexus in an office-based setting without surgical intervention. Neotonus markets a non-surgical device to deliver extracorporeal magnetic neurostimulation. Other companies may also enter the U.S. market, including Boston Scientific, which is conducting clinical trials in the U.S. for Bion<sup>®</sup> Microstimulator, a device implanted with a needle-like instrument to stimulate the pudendal nerve, which is CE mark approved for the treatment of urinary urge incontinence.

Our Urgent PC system also competes with medications such as Detrol<sup>®</sup> and Toviaz<sup>®</sup> (both by Pfizer Inc.); Ditropan<sup>®</sup> (manufactured by Alza Corporation and distributed by Ortho McNeil Pharmaceuticals); Enablex<sup>®</sup> (Novartis); and Vesicare<sup>®</sup> (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 competes effectively against these drugs for many patients because these drugs can have unwanted side effects such as dry mouth, vision problems or constipation.

Soft-tissue injectable urethral bulking agents competing directly with Macroplastique both outside and in the United States include: FDA-approved Contigen<sup>®</sup> distributed by C.R. Bard, Inc.; Deflux<sup>®</sup> (FDA-approved for vesicoureteral reflux use only) manufactured by Q-Med AB; Durasphere<sup>®</sup> (FDA-approved for female SUI) manufactured by Carbon Medical Technologies and distributed by Coloplast; and Coaptite<sup>®</sup> manufactured by BioForm, Inc. and distributed by Boston Scientific. We understand that C.R. Bard, Inc. will discontinue selling Contigen in about twelve months. We believe that Macroplastique competes favorably against these products because it will not degrade, resorb or migrate, has no special preparation or storage requirements and does not require the patient to have a skin allergy test prior to the procedure.

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.

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### *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 application. FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

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

In October 2006, we received pre-market approval for the use of Macroplastique to treat female stress urinary incontinence. 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 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.

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### ***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 applications; 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, 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 FDA. We have obtained regulatory approvals in countries where required of us to sell our products. We believe the extent and complexity of regulations for medical devices such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase.

### **Patents, Trademarks and Licenses**

Our success depends in part on our ability to obtain and maintain patent protection for our products, preserve our trademarks and trade secrets and operate without infringing the proprietary rights of third parties. We seek to protect our technology by filing 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 acquired one granted and several pending patents related to the Urgent PC system when we purchased certain intellectual property assets from CystoMedix in April 2007, and have subsequently filed several related patent applications, some of which are currently pending. In addition, we hold multiple patents covering soft-tissue bulking materials, processes and applications. As of the date of this prospectus, we have seven issued patents in the United States and 17 granted patents in the United Kingdom, Japan, Germany, France, Spain, Italy, Portugal, The Netherlands and Canada. Our patents will expire in the United States at various times between 2011 and 2027 and in other countries between 2013 and 2019.

There can be no assurance that any of our issued patents are of sufficient scope or strength to provide meaningful protection. In addition, there can be no assurance that any of our current or future United States and foreign patents will not be challenged, narrowed, invalidated or circumvented by competitors or 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.

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, however, these measures will prevent the unauthorized disclosure or use of this information or that others will not be able to independently develop this information.

We acquired the “Urgent” registered trademark in April 2007 from CystoMedix. We have registered “Uroplasty,” “Macroplastique,” “VOX,” “PTQ” and “Bioplastique” trademarks with the U.S. Patent and Trademark Office and throughout the European Union.

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We have certain royalty agreements under which we pay royalties on sales of Macroplastique, VOX, PTQ and the Macroplastique Implantation System.

**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 \$1.8 million and \$2.6 million for fiscal 2010 and 2009, 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 dollars 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, if 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 2010 and 2009 has not had a material effect upon our capital expenditures, earnings or competitive position.

**Dependence on Major Customers**

During fiscal 2010 or 2009, none of our customers accounted for 10% or more of our net sales.

**Backlog**

We did not have significant backlog at fiscal yearend 2010 or 2009. We process customer orders generally within one or two days of receipt of the order.

**Employees**

As of March 31, 2010, we had 64 employees, of which 60 were full-time and 4 were part-time. No employee was subject to a collective bargaining agreement. We believe we maintain good relations with our employees.

**Incorporation and Current Subsidiaries**

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

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

- Uroplasty BV                      Incorporated in The Netherlands, distributes the Urgent PC, 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 Urgent PC, 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.

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### **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, 2010, we had an accumulated deficit of approximately \$26.6 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 for 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 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.***

Our success depends, to a significant extent, on the availability of reimbursement for the cost of our products from third-party payers, such as government health authorities, private health insurance plans and managed care organizations. There is no uniform policy for reimbursement in the United States or foreign countries. Within the United States, reimbursement coverage is often payer-specific, affecting the consistency and speed of reimbursement payments our customers receive and the inclination of physicians to use our products. Changes in the extent or type of coverage or a reduction in reimbursement rates can cause a decline in purchases of our products, which can materially adversely affect their marketability.

As a relatively new therapy, PTNS using the Urgent PC system has historically not been assigned a reimbursement code unique to the technology. During our first fiscal quarter of 2009, the AMA advised the medical community that the previously recommended unique, listed CPT code for reimbursement for Urgent PC treatments be replaced with an unlisted code. As a result, some third-party insurance carriers are delaying or denying reimbursement while certain other carriers are reassessing their coverage and reimbursement policies for Urgent PC treatments. However, many other third party payers, under a published positive coverage policy or on a case-by-case basis, continue to provide reimbursement for Urgent PC treatments.

During the past eighteen months we have sponsored and received favorable results from clinical trials designed to demonstrate the efficacy of our Urgent PC system, with results published in peer-reviewed medical journals, both to encourage reimbursement and to support our February 2010 application to the AMA for a unique, listed CPT code for PTNS treatments. The AMA has advised us that they have assigned a unique, listed CPT code for PTNS. This decision is expected to be published in the Federal Register by the Centers for Medicare and Medicaid Services by October 2010. Nevertheless, the code will not become effective until January 2011, the suggested reimbursement amount for Urgent PC treatments is not yet established, the exact CPT code number is not yet assigned, and no private payers or governmental agencies have agreed, or considered to agree, to provide reimbursement on the basis of this new CPT code prior to its effective date. While we believe the availability of a unique, listed CPT code will encourage broader use of our Urgent PC, there is no assurance that additional payers will agree to create coverage policies or that the policies, if they create, will provide adequate reimbursement.

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

In addition to availability of third-party reimbursement, market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefits, cost-effectiveness and third party reimbursement 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.

***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 of direct sales and independent 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.

***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 2010, sales of our Urgent PC system and Macroplastique accounted for approximately 40% and 47%, respectively, of our total net sales, and the decline in our Urgent PC sales has significantly negatively impacted our business. In fiscal 2009, these products accounted for 51% and 36%, respectively, of our total net sales. If demand for our two product lines decline, our revenues and business prospects may continue to suffer.

***We likely will 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

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protecting our proprietary rights. Because we have yet to achieve profitability and generate positive cash flows, we likely will need to raise additional financing to support our operations and planned growth activities in the future. 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. There can be no guarantee that we will be successful, as we currently have no committed sources of, or other arrangements with respect to, additional equity or debt financing. 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;
- recalling or seizing our products; or
- withdrawing or denying approvals or clearances for our products.

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

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

Medical product law and regulation in the United States, and the severity with which they are enforced, are subject to change and periodic fluctuation based upon both political movement and high profile events and cases. Recently the United States Congress adopted, and President Obama signed into law, the Patient Protection and Affordable Care Act: health care reform legislation that, among other things, is intended to expand access to and control costs of health care. Although this new law is designed primarily to deal with third-party payers, changes in the manner such payers do business could impact reimbursement for medical products, such as ours, in ways we cannot predict. Further, the Food and Drug Administration 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.

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

We may rely on our distributors 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 net 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 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

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competitive advantage. Our patents and patent applications if issued may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us.

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

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

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

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

### ***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

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requirements. Canada and the European Union also impose requirements on quality systems of manufacturers, who are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Further, our suppliers are also subject to these regulatory requirements. Failure by any of our suppliers or us to comply with these requirements could prevent us from obtaining or retaining approval for and marketing of our products.

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

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

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

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

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

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

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

***Recent deterioration in the economy and credit markets may adversely affect our results of operations and our plans for expansion.***

Although our ability to finance expansion of our business, including acquisitions, is dependent upon our operating and financial performance, it is also dependent upon the general availability of credit and prevailing market conditions. As widely reported, the global credit markets and financial services industry have been experiencing a period of dramatic upheaval that has diminished liquidity and credit availability. Further, the general decline in consumer confidence and economic growth, coupled with increases in unemployment rates and uncertainty about economic stability, may impact the willingness of medical consumers to incur unreimbursed medical expense or the higher deductibles that increasingly are required for reimbursed medical expense. This decreasing confidence may cause some consumers to delay medical care and, eventually, the use of our products. We cannot assure you that this economic downturn has ended or that there will not be further deterioration in the global economy, financial markets and consumer confidence. Although the ultimate outcome of these events cannot be predicted, a prolonged economic downturn could have a material adverse effect on the level of our sales and our ability to borrow money in the credit markets to finance expansion.

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***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 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, including our former parent, Bioplasty, Inc. 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 49% of our sales in fiscal 2010 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 new export licensing requirements;
- local political and economic instability;
- fluctuations in the value of the U.S. dollar relative to foreign currencies;
- difficulties in recruiting and maintaining distributors and staff in remote locations, including sales people;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- foreign taxation compliance and penalties;
- pricing pressure that we may experience internationally;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; and
- difficulties in enforcing or defending intellectual property rights.

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

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

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

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### ***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 NYSE AMEX. 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, 2010, we have 2,037,500 shares of our common stock subject to outstanding options and 2,066,928 shares of our common stock subject to outstanding warrants. Warrants to purchase 1,180,928 shares of our common stock, at an exercise price of \$4.75 per share, expired in April 2010.

### ***We will be exposed to risks relating to evaluations of controls required by Section 404 of the Sarbanes-Oxley Act.***

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. Although our management has been required to evaluate the adequacy of our internal controls over financial reporting, absent further legislative actions, our independent auditors will be required to opine as to the adequacy of such internal controls for the first time for our fiscal 2011. While we anticipate being able to fully implement the requirements by the March 31, 2011 deadline, such requirements will likely increase audit costs, and if our auditors are unable to opine, our filings could be delayed and cause us to incur other costs. If we are not able to implement the requirements in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, including the SEC. This type of action could

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adversely affect confidence in our company and our ability to access capital markets and could cause our stock price to decline.

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

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

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

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

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

### **Item 2. Description of Property**

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

### **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.* As of the date hereof, there is only a limited public trading market for our common stock.

Our common stock is listed on the NYSE AMEX (fka The American Stock Exchange) under the symbol “UPI.”

The following table sets forth the high and low closing prices for our common stock for our fiscal years ended March 31, 2010 and 2009 as reported on the NYSE AMEX.

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
Fiscal Year Ended March 31, 2009		
First Quarter	\$3.00	\$3.82
Second Quarter	2.25	3.30
Third Quarter	0.80	2.27
Fourth Quarter	0.36	1.15

As of March 31, 2010, we had approximately 454 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, 2010.

	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</u>	<u>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)</u>
<b>Equity Compensation Plans Approved by Security Holders<sup>(1)</sup></b>	1,097,500	\$ 2.38	1,497,500
<b>Equity Compensation Plans Not Approved by Security Holders<sup>(2)</sup></b>	940,000	\$ 4.02	—
<b>Total</b>	2,037,500	\$ 3.14	1,497,500

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

(2) Represents (i) non-qualified options to purchase 30,000 shares of our common stock (all of which are vested), at a weighted average exercise price of \$3.17 per share, issued under our 1995 Stock Option Plan, which was not approved by our stockholders, and (ii) non-qualified options to purchase 910,000 options (all of which are vested), at a weighted average exercise price of \$4.05, 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<sup>®</sup> system, which we believe is the only FDA-approved minimally invasive, office-based neuromodulation therapy for the treatment of urinary urgency, urinary frequency, and urge incontinence — symptoms often associated with overactive bladder (OAB); and Macroplastique<sup>®</sup>, 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 is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence and vesicoureteral reflux

Our sales growth during fiscal 2007 and 2008 was largely attributable to rapid market acceptance of our Urgent PC product in the U.S. However, our sales performance in the U.S. was impacted by the American Medical Association's (AMA) advice to the medical community, during our first fiscal quarter of 2009, that the previously recommended unique, listed CPT code for reimbursement for Urgent PC treatments be replaced with an unlisted code. As a result, some third-party insurers are delaying or denying reimbursement while certain other insurers are reassessing their coverage and reimbursement policies for Urgent PC treatments. However, many other third party payers, under a published positive coverage policy or on a case-by-case basis, continue to provide reimbursement for Urgent PC treatments.

Starting in the second half of fiscal 2009, sales over corresponding year-ago periods of our Urgent PC system declined and continued to do so in fiscal 2010 because of reimbursement-related issues, although sales stabilized at around \$0.9 million to \$1 million per quarter in fiscal 2010. We expect Urgent PC sales in the U.S. will likely decline further in fiscal 2011 and we do not expect the sales to return to prior historical levels until after we obtain a unique, listed CPT code and payers create coverage policies that provide adequate reimbursement.

A major part of our strategy, supported by publication of clinical studies in peer-reviewed journals in the U.S., has been to obtain a unique, listed Current Procedure Technology (CPT) code for PTNS, and expand third-party reimbursement coverage of Urgent PC treatments in the U.S. Additionally, we continue to implement a comprehensive program designed to educate Medicare carriers and private payer medical directors about the benefits and clinical study results of Urgent PC. During the past eighteen months we have sponsored and received favorable results from clinical trials designed to demonstrate the efficacy of our Urgent PC system, and to date five new articles have been published in U.S. medical journals on Urgent PC. The most recent publications in *The Journal of Urology*<sup>®</sup> include the results of the 12-week OrBIT clinical trial, published in the September 2009 issue, the long-term phase of the OrBIT clinical trial, published in the January 2010 issue, and the 12-week SUmiT clinical trial, published in the April 2010 issue.

We submitted an application for a unique, listed CPT code to the AMA for consideration at the CPT Editorial Panel Meeting in February 2010. The AMA has advised us that they have assigned a unique, listed CPT code for PTNS. This decision is expected to be published in the Federal Register by the Centers for Medicare and

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Medicaid Services by October 2010. Nevertheless, the code will not become effective until January 2011, the suggested reimbursement amount for Urgent PC treatments is not yet established, the exact CPT code number is not yet assigned, and no private payers or governmental agencies have agreed, or considered to agree, to provide reimbursement on the basis of this new CPT code prior to its effective date. While we believe the availability of a unique, listed CPT code will encourage broader use of our Urgent PC, there is no assurance that additional payers will agree to create coverage policies or that the policies, if they create, will provide adequate reimbursement.

We have increased our emphasis on sales of our Macroplastique product in the United States. We have expanded our marketing activities and conducted specific sales training programs with our U.S. sales representatives to increase their ability to understand and advise clinicians as to its use and benefits with the expectation of increased sales. As a result, fiscal 2010 Macroplastique sales in the U.S. about doubled over fiscal 2009 and we anticipate increased sales in fiscal 2011.

### **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 Uroplasty management, 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 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.

*Accounts Receivable.* We carry our accounts receivable at the original invoice amount less an estimate made for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts 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

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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 were translated in accordance with the provisions of ASC 830 "Foreign Currency Matters." Under this Statement, 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 report assets to be disposed of at the lower of the carrying amount or fair value less costs to sell. We did not record any impairment charge in fiscal years 2010 or 2009.

*Share-Based Compensation.* We account for share-based compensation costs under ASC 718, "Compensation — Stock Compensation". ASC 718 requires that we recognize the compensation cost relating to share-based payment transactions, including grants of employee stock options, in our financial statements. We must measure that cost based on the fair value of the equity or liability instruments issued. 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.

*Defined Benefit Pension Plans.* We have a liability attributed to defined benefit pension plans we offered to certain former and current employees. 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.

*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, 2010, we have generated approximately \$26 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.

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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 the issuance of our common stock in the December 2006 follow-on public offering resulted in an "ownership change" under Section 382. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 may be limited.

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

### Results of Operations

*Net Sales.* In fiscal 2010, net sales were \$11.9 million, representing a \$2.9 million or 20% decrease compared to net sales of \$14.7 million in fiscal 2009. Excluding the translation impact of fluctuations in foreign currency exchange rates, net sales decreased by approximately 19%.

Our fiscal 2010 sales over the corresponding periods in fiscal 2009 declined 31% in the first half and declined 4% in the second half. In the U.S., in the first half of fiscal 2009 we had growing success with sales of our Urgent PC product, but, because of reimbursement-related issues, those sales started to decline in the second half of fiscal 2009 and continued to do so in fiscal 2010. Partially offsetting this decline was the growing sales of Macroplastique product in the U.S. Additionally, first half sales in fiscal 2010 to customers outside of the U.S. declined over the corresponding year-ago period primarily due to increased competition in sales of our Macroplastique products in Europe.

Sales to customers in the U.S. in fiscal 2010 totaled \$6.1 million, representing a \$1.9 million or 24% decline compared to \$8.0 million in fiscal 2009. We attribute this decline to the decline in sales of our Urgent PC product, partially offset by an increase in sales of our Macroplastique product. Sales in the U.S. of our Urgent PC product declined 44% to \$3.8 million in fiscal 2010, from \$6.8 million in fiscal 2009. The trend in decline of our Urgent PC sales over corresponding year-ago periods began in the second half of fiscal 2009 due to reimbursement related issues. Urgent PC sales in fiscal 2010 have stabilized at around \$0.9 million to \$1 million per quarter. Sales in the U.S. of Macroplastique product increased 95% to \$2.2 million in fiscal 2010, from \$1.1 million in fiscal 2009. Sales of Macroplastique product have steadily increased because of our increased sales and marketing focus.

In fiscal 2011, we anticipate sales of Macroplastique product in the U.S. to continue to grow as we expect to benefit from our continued sales and marketing focus. We do not expect that we will be able to return to the historic sales level of Urgent PC product in the U.S. until after a unique, listed CPT becomes effective in January 2011 and payers create coverage policies that provide adequate reimbursement.

Sales to customers outside the U.S. were \$5.8 million in fiscal 2010, a decline of 14%, from \$6.8 million in fiscal 2009. Excluding the translation impact of fluctuations in foreign currency exchange rates, sales declined by approximately 12%. We believe the sales decrease is mainly attributed to increased competition from a newly-introduced product against our Macroplastique product. In addition, in fiscal year 2010 we discontinued in the United Kingdom our I-Stop urethral sling product which accounted for approximately \$191,000 of sales in fiscal 2009.

*Gross Profit:* Gross profit was \$9.8 million in fiscal 2010 and \$12.5 million in fiscal 2009, or 83% and 85% of net sales in the respective periods. We attribute the lower gross profit percentage primarily to a decrease in manufacturing capacity utilization as a result of the decline in sales, changes in sales product mix, and the negative impact of changes in the currency exchange rates on our foreign currency-denominated sales. The first two factors each had an approximately 0.7 percentage point negative effect and the last factor had an approximately 0.2 percentage point negative effect on the gross profit percentage.

*General and Administrative Expenses (G&A):* G&A expenses decreased \$630,000 from \$3.4 million in fiscal 2009 to \$2.8 million in fiscal 2010. Included in fiscal 2009 is a \$306,000 non-cash, share-based compensation charge, compared to a charge of \$191,000 in fiscal 2010. Excluding share-based compensation charges, G&A expenses decreased by \$515,000 in fiscal 2010 compared to fiscal 2009. G&A expenses decreased primarily because of a \$227,000 decrease in professional and consulting fees, a \$148,000 decrease in bad debt expenses, a \$39,000 decrease in travel costs, and other reductions as we implemented cost reduction measures. The

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decrease of professional and consulting fees is primarily attributed to reduction of audit and tax fees, and reductions in consulting for investor relations and information services. The decrease of bad debt expense is mainly attributed to a \$44,000 recovery of a customer receivable in fiscal 2010 for which we had reserved \$82,000 in fiscal 2009. We have implemented concentrated efforts to reduce expenses until reimbursement in the U.S. for Urgent PC recovers and the economy improves.

*Research and Development Expenses (R&D):* R&D expenses decreased from \$2.6 million in fiscal 2009 to \$1.8 million in fiscal 2010. The decrease in fiscal 2010 is attributed to a \$667,000 decrease in spending for clinical studies, a \$44,000 decrease in travel costs and a \$32,000 decrease in consulting expense, offset partially by an \$70,000 increase in compensation-related costs. We undertook clinical studies that we anticipate may assist us in obtaining a unique, listed CPT code that will encourage broader use of our Urgent PC. In fiscal 2010 we spent \$0.5 million for clinical studies compared to \$1.3 million in fiscal 2009. While we do not anticipate spending any more for clinical studies to support our efforts to obtain a unique, listed CPT code, we expect to spend approximately \$0.4 million in fiscal 2011 for ongoing marketing efforts and to meet regulatory requirements.

*Selling and Marketing Expenses (S&M):* S&M expenses decreased from \$9.3 million in fiscal 2009 to \$7.6 million in fiscal 2010. We attribute the decrease to a \$368,000 decrease in commissions due to the decrease in sales, a \$415,000 decrease in compensation-related costs on lower headcount and share-based charges, a \$295,000 decrease in travel costs, a \$333,000 decrease in cost to support our marketing activities and a \$111,000 decrease in consultancy costs, mainly related to reimbursement for our Urgent PC product. Although we have maintained our assembled U.S. sales force and redirected some of their effort to our Macroplastique product line until reimbursement for Urgent PC stabilizes, we have taken steps to control other sales and marketing expenses.

*Amortization of Intangibles:* Amortization of intangibles was \$846,000 in each of the fiscal years 2010 and 2009. 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 \$40,000 and \$159,000 for fiscal years 2010 and 2009, respectively. The decline in net other income is attributed primarily to the decline in interest income on lower cash balance and interest rates.

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 loss of \$38,000 and \$14,000 for fiscal years 2010 and 2009, respectively.

*Income Tax Expense (Benefit):* We recorded income tax expense of \$41,000 and \$115,000 for fiscal years 2010 and 2009, respectively. In fiscal 2009 we recorded an income tax charge of \$67,000 for a settlement we reached with the Netherlands tax authorities for income tax liability for fiscal years 2004 to 2007. 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

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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 such 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 2010 and 2009 was approximately \$1.6 million and \$1.7 million, respectively.

	Years Ended March 31,	
	2010	2009
<b>Gross Profit</b>		
GAAP gross profit	\$9,804,347	\$12,458,207
% of sales	83%	85%
Share-based compensation	27,400	42,818
Depreciation expenses	58,105	52,432
<hr/>		
Non-GAAP gross profit	9,889,852	12,553,457
<b>Operating Expenses</b>		
GAAP operating expenses	13,006,634	16,080,583
Share-based compensation	387,107	706,788
Depreciation expenses	234,419	237,844
Amortization expenses	845,553	845,524
<hr/>		
Non-GAAP operating expenses	11,539,555	14,290,427
<b>Operating Loss</b>		
GAAP operating loss	(3,202,287)	(3,622,376)
Share-based compensation	414,507	749,606
Depreciation expenses	292,524	290,276
Amortization expenses	845,553	845,524
<hr/>		
Non-GAAP operating loss	\$(1,649,703)	\$(1,736,970)

**Liquidity and Capital Resources**

*Cash Flows.* At March 31, 2010, our cash and cash equivalent and short-term investments balances totaled \$5.8 million. At March 31, 2010, we had working capital of approximately \$6.1 million. In fiscal 2010, we used \$1.9 million of cash in operating activities, compared to \$1.4 million of cash used in fiscal 2009. We attribute the increase in cash used in operating activities primarily to a reduction in working capital liabilities, primarily attributed to reduction in compensation-related accruals, offset partially by reduction in inventories.

In fiscal 2010 we used approximately \$111,000 to purchase property, plant and equipment compared with approximately \$200,000 in fiscal 2009.

In fiscal 2009 we used approximately \$456,000 of cash in financing activities to fully retire our term debt.

*Sources of Liquidity.* On October 30, 2009 we renewed our credit line with Venture Bank. The agreement provides for a credit line of up to \$2 million secured by the assets of our company. We may borrow up to 50% (to a maximum of \$500,000) of the value of our eligible inventory on hand and 80% of the value of our eligible U.S. accounts receivable; provided, however, our total liabilities, inclusive of the amount borrowed, may not exceed our tangible net worth. To be eligible to borrow any amount, we must maintain a minimum

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tangible net worth of \$5 million. At March 31, 2010 we had tangible net worth of approximately \$6.7 million, and had no borrowings outstanding under this agreement. We estimate we had a borrowing capacity of approximately \$0.6 million at March 31, 2010. Interest on the loan is charged at a per annum rate of the greater of 7.5% or one percentage point over the prime rate (3.25% prime rate on March 31, 2010).

Uroplasty BV, our subsidiary, has an agreement with Rabobank of The Netherlands for a €500,000 (approximately \$670,000) 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 (4.65% base rate on March 31, 2010), subject to a minimum interest rate of 3.5% per annum. At March 31, 2010, we had no borrowings outstanding on this credit line.

We believe we have sufficient liquidity to meet our needs over the next twelve months. However, we may need to raise additional financing to support our operations and planned growth activities in the future as we have yet to achieve profitability and generate positive cash flows. To achieve profitability, 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 are unable to raise the needed funds, we may need to curtail our operations including product development, clinical studies and sales and marketing activities. This would adversely impact our future business and prospects. Ultimately, we will need to achieve profitability and generate positive cash flows from operations to meet our cash needs and grow our business.

*Commitments and Contingencies.* We expect to continue to incur significant 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 2012 and 2013. 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.

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The following table presents the sensitivity of our funded status as of March 31, 2010, and fiscal 2011 pension expense to the following changes in key assumptions:

	<b>Increase/(Decrease) Funded Status at March 31, 2010</b>	<b>Increase/(Decrease) Fiscal 2011 pension expense</b>
<b>Assumption:</b>		
Increase in discount rate by 1 percentage point	\$ 241,000	\$ (24,000)
Decrease in discount rate by 1 percentage point	(326,000)	30,000
Increase in estimated return on assets by 1 percentage point	-	(5,000)
Decrease of estimated return on assets by 1 percentage point	-	5,000
Increase in inflation rate by 1 percentage point	(333,000)	58,000
Decrease in inflation rate by 1 percentage point	275,000	(48,000)
Increase in compensation increase by 1 percentage point	(273,000)	52,000
Decrease in compensation increase by 1 percentage point	11,000	(2,000)

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 date was 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 estimated at approximately \$85,000 over 12 months.

**Recent Accounting Pronouncements**

In January 2010, the FASB issued Accounting Standards Update No. 2010-06, "Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements" (ASU 2010-06). This update provides amendments to Subtopic 820-10 that require new disclosures and clarify existing disclosures. Part of the ASU was effective for our 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 become effective starting our fourth quarter of fiscal 2011. We do not anticipate adoption to have an impact on our financial position or results of operations.

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, "Measuring Liabilities at Fair Value" (ASU 2009-05). This Standards Update provides amendments to ASC Topic 820, "Fair Value Measurements and Disclosure" for the fair value measurement of liabilities when a quoted price in an active market is not available. This ASU was effective for our third quarter of our fiscal 2010 and the adoption did not have an impact on our financial position or results of operations.

In June 2009, the FASB issued SFAS No. 168, "The FASB Accounting Codification and the Hierarchy of Generally Accepted Accounting Principles." SFAS 168 replaced FASB Statement No. 162, "The Hierarchy of Generally Accepted Accounting Principles," and establishes the FASB Accounting Standards Codification™ (Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles (GAAP). SFAS 168 was effective for interim and annual periods ending after September 15, 2009. We now use the new Codification when referring to GAAP in our interim financial statements. The adoption of the SFAS 168 changes our references to U.S. GAAP, but does not have an impact on our financial position or results of operations.

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In May 2009, the FASB issued ASC 855, “*Subsequent Events*.” This Statement incorporates guidance into accounting literature that was previously addressed only in auditing standards. The statement refers to subsequent events that provide additional evidence about conditions that existed at the balance-sheet date as “recognized subsequent events.” Subsequent events which provide evidence about conditions that arose after the balance sheet date but prior to the issuance of the financial statements are referred to as “non-recognized subsequent events.” We adopted this standard effective April 1, 2009 — see Note 17.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

Not Applicable

### **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**

*Disclosure Controls and Procedures.* Under the supervision and with the participation of our management, including, our President and Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934 (the “Exchange Act”). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, in a manner that allows timely decisions regarding required disclosure.

*Internal Control Over Financial Reporting.* Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company’s assets that could have a material effect on the financial statements.

The design of system of control over financial reporting inherently has limitations. Controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the control. Therefore, no evaluation of a cost-effective system of controls can provide absolute assurance that all control issues and instances of fraud, if any, will be detected.

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

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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, 2010. There were no changes in our internal control over financial reporting during the quarter ended March 31, 2010, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

This annual report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the SEC that permit us to provide only management’s report in this annual report.

### **Item 9B. Other Information**

None.

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PART III

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**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 is 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:

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Consolidated Balance Sheets	F-3
Consolidated Statement of Operations	F-5
Consolidated Statements of Shareholders' Equity and Comprehensive Loss	F-6
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2. Financial Statement Schedules:

Schedule II — Valuation and Qualifying Accounts

	<b>Balance at beginning of fiscal year</b>	<b>Additions charged to costs and expenses</b>	<b>Written off, less recoveries</b>	<b>Effects of foreign currency fluctuations</b>	<b>Balance at end of fiscal year</b>
<b>Allowance for doubtful accounts and sales returns</b>					
Fiscal year ended March 31, 2010	\$ 177,000	\$ 19,000	\$ (126,000)	\$8,000	\$ 78,000
Fiscal year ended March 31, 2009	\$ 82,000	\$ 341,000	\$ (245,000)	\$(1,000)	\$ 177,000

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)*

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Number	Description
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)*
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	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)
10.11	Form of Selling Agent's warrant (Incorporated by reference to Exhibit 4.3 to Registrant's Form SB-2/A 1 filed November 27, 2006 (File No. 333-138267))
10.12	Form of Registration Rights Agreement dated as of August 7, 2006, by and among Uroplasty, Inc., and the investors identified named therein (Incorporated by reference to Exhibit 10.34 to Registrant's Form 8-K filed August 8, 2006)
10.13	Form of Warrant dated August 7, 2006 (Incorporated by reference to Exhibit 10.33 to Registrant's Form 8-K filed August 8, 2006)
10.14	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)
10.15	Business Loan Agreement and related Promissory Note dated October 30, 2009 with Venture Bank (Incorporated by reference to Exhibit 10.17 to Registrant's Form 10-Q filed November 2, 2009)
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
24.1	Power of Attorney
23.1	Consent of Independent Registered Public Accounting Firm — Grant Thornton LLP
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

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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 28, 2010 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
<u>/s/ David B. Kaysen</u> David B. Kaysen	President, Chief Executive Officer and Director (Principal Executive Officer)	May 28, 2010
<u>/s/ Mahedi A. Jiwani</u> Mahedi A. Jiwani	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	May 28, 2010
<u>/s/ R. Patrick Maxwell*</u> R. Patrick Maxwell	Chairman of the Board of Directors	May 28, 2010
<u>/s/ Thomas E. Jamison*</u> Thomas E. Jamison	Director	May 28, 2010
<u>/s/ Lee A. Jones*</u> Lee A. Jones	Director	May 28, 2010
<u>/s/ James P. Stauner*</u> James P. Stauner	Director	May 28, 2010
<u>/s/ Sven A. Wehrwein*</u> Sven A. Wehrwein	Director	May 28, 2010

\* 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.



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UROPLASTY, INC. AND SUBSIDIARIES

Index to Consolidated Financial Statements  
March 31, 2010 and 2009

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**REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM**

The Board of Directors and Shareholders  
Uroplasty, Inc.

We have audited the accompanying consolidated balance sheets of Uroplasty, Inc. (a Minnesota corporation) and subsidiaries (together “the Company”) as of March 31, 2010 and 2009, and the related consolidated statement of operations, shareholders’ equity and comprehensive loss, and cash flows for each of the two years in the period ended March 31, 2010. Our audits of the basic financial statements included the financial statement schedule listed in the index appearing under Item 15. These financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Uroplasty, Inc. and subsidiaries as of March 31, 2010 and 2009, and the results of their operations and their cash flows for each of the two years in the period ended March 31, 2010 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Grant Thornton LLP  
Minneapolis, Minnesota  
May 28, 2010

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

	<u>2010</u>	<u>2009</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$2,311,269	\$3,276,299
Short-term investments	3,500,000	4,500,000
Accounts receivable, net	1,287,440	1,214,049
Inventories	341,497	495,751
Income tax receivable	23,820	-
Other	<u>237,321</u>	<u>279,898</u>
Total current assets	7,701,347	9,765,997
Property, plant, and equipment, net	1,230,771	1,401,229
Intangible assets, net	2,533,095	3,378,648
Prepaid pension asset	-	66,130
Deferred tax assets	<u>108,530</u>	<u>68,793</u>
Total assets	<u>\$11,573,743</u>	<u>\$14,680,797</u>

See accompanying notes to consolidated financial statements.

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

	<u>2010</u>	<u>2009</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$485,594	\$604,593
Current portion – deferred rent	35,000	35,000
Income tax payable	10,000	56,785
Accrued liabilities:		
Compensation	903,057	983,052
Other	212,028	248,568
<b>Total current liabilities</b>	<b>1,645,679</b>	<b>1,927,998</b>
Deferred rent – less current portion	112,500	147,576
Accrued pension liability	601,037	296,646
<b>Total liabilities</b>	<b>2,359,216</b>	<b>2,372,220</b>
<b>Commitments and contingencies</b>	<b>-</b>	<b>-</b>
Shareholders' equity:		
Common stock \$.01 par value; 40,000,000 shares authorized, 14,946,540 shares issued and outstanding at March 31, 2010 and 2009	149,465	149,465
Additional paid-in capital	36,178,126	35,763,619
Accumulated deficit	(26,617,161)	(23,413,350)
Accumulated other comprehensive loss	(495,903)	(191,157)
<b>Total shareholders' equity</b>	<b>9,214,527</b>	<b>12,308,577</b>
<b>Total liabilities and shareholders' equity</b>	<b>\$11,573,743</b>	<b>\$14,680,797</b>

See accompanying notes to consolidated financial statements.

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

	<b>2010</b>	<b>2009</b>
Net sales	\$11,863,202	\$14,742,182
Cost of goods sold	2,058,855	2,283,975
Gross profit	9,804,347	12,458,207
Operating expenses		
General and administrative	2,798,900	3,428,959
Research and development	1,785,405	2,551,075
Selling and marketing	7,576,776	9,255,025
Amortization	845,553	845,524
	13,006,634	16,080,583
Operating loss	(3,202,287)	(3,622,376)
Other income (expense)		
Interest income	92,736	196,714
Interest expense	(14,476)	(17,160)
Foreign currency exchange loss	(37,552)	(13,843)
Other, net	(853)	(6,747)
	39,855	158,964
Loss before income taxes	(3,162,432)	(3,463,412)
Income tax expense	41,379	114,708
Net loss	\$(3,203,811)	\$(3,578,120)
Basic and diluted loss per common share	\$(0.21)	\$(0.24)
Weighted average common shares outstanding:		
Basic and diluted	14,944,354	14,922,502

See accompanying notes to consolidated financial statements.

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY AND COMPREHENSIVE LOSS  
 Years ended March 31, 2010 and 2009

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
Balance at March 31, 2008	14,916,540	\$149,165	\$35,014,313	\$(19,835,230)	\$ 274,473	\$15,602,721
Share-based consulting and compensation expense	30,000	300	749,306	-	-	749,606
Comprehensive loss	-	-	-	(3,578,120)	(465,630)	(4,043,750)
Balance at March 31, 2009	14,946,540	149,465	35,763,619	(23,413,350)	(191,157)	12,308,577
Share-based compensation expense	-	-	414,507	-	-	414,507
Comprehensive loss	-	-	-	(3,203,811)	(304,746)	(3,508,557)
Balance at March 31, 2010	14,946,540	\$149,465	\$36,178,126	\$(26,617,161)	\$(495,903)	\$ 9,214,527

See accompanying notes to consolidated financial statements.

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS  
 Years ended March 31,

	2010	2009
<b>Cash flows from operating activities:</b>		
Net loss	\$(3,203,811)	\$(3,578,120)
<b>Adjustments to reconcile net loss to net cash used in operations:</b>		
Depreciation and amortization	1,138,077	1,135,800
Loss on disposal of equipment	853	6,757
Share-based consulting expense	-	60,093
Share-based compensation expense	414,507	689,513
Deferred income taxes	(39,741)	17,594
Deferred rent	(35,000)	(35,000)
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	(56,052)	918,959
Inventories	172,723	(19,512)
Other current assets and income tax receivable	(42,827)	50,086
Accounts payable	(127,355)	(25,781)
Accrued liabilities	(152,776)	(655,186)
Accrued pension liability, net	39,159	13,111
<b>Net cash used in operating activities</b>	<b>(1,892,243)</b>	<b>(1,421,686)</b>
<b>Cash flows from investing activities:</b>		
Proceeds from sale of short-term investments	5,500,000	14,157,410
Purchase of short-term investments	(4,500,000)	(12,391,373)
Purchases of property, plant and equipment	(111,154)	(199,704)
Proceeds from sales of equipment	2,800	-
Payments for intangible assets	-	(23,282)
<b>Net cash provided by investing activities</b>	<b>891,646</b>	<b>1,543,051</b>
<b>Cash flows from financing activities:</b>		
Repayment of debt obligations	-	(455,913)
<b>Net cash used in financing activities</b>	<b>-</b>	<b>(455,913)</b>
Effect of exchange rates on cash and cash equivalents	35,567	(269,197)
<b>Net decrease in cash and cash equivalents</b>	<b>(965,030)</b>	<b>(603,745)</b>
Cash and cash equivalents at beginning of year	3,276,299	3,880,044
<b>Cash and cash equivalents at end of year</b>	<b>\$2,311,269</b>	<b>\$3,276,299</b>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the year for interest	\$7,697	\$13,612
Cash paid during the year for income tax	135,032	18,335

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
March 31, 2010 and 2009

1. Summary of Significant Accounting Policies

**Nature of Business.** We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our primary focus is on two products: our Urgent PC<sup>®</sup> system, which we believe is the only FDA-approved minimally invasive, office-based neuromodulation therapy for the treatment of urinary urgency, urinary frequency, and urge incontinence — symptoms often associated with overactive bladder (OAB); and Macroplastique<sup>®</sup>, 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 is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence and vesicoureteral reflux.

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

The Urgent PC system uses percutaneous tibial nerve stimulation (PTNS) to deliver 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 neurostimulation therapy, and we believe our intellectual property portfolio provides us a competitive advantage.

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

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

**Revenue Recognition.** We recognize revenue when persuasive evidence of an arrangement exists, title and risk of ownership have passed, the sales price is fixed or determinable and collectability is reasonably assured. Generally, these criteria are met at the time the product is shipped to the customer. We include shipping and handling charges billed to customers in net sales, and include such costs incurred by us in cost of sales. Typically our agreements contain no customer acceptance provisions or clauses. We sell our products to end users and to distributors. Payment terms range from prepayment to 60 days. The distributor payment terms are not contingent on the distributor selling the product to end users. Customers do not have the right to return unsold products except for warranty claims. We offer customary product warranties. The allowance for sales returns was \$67,000 and \$63,000 at March 31, 2010 and 2009, respectively. During fiscal 2010 and 2009, no customers accounted for 10% or more of our net 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.

**Use of Estimates.** The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires of us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates. Our significant accounting policies and estimates include revenue recognition, accounts receivable, valuation of inventory, foreign currency translation/transactions, the determination of recoverability of long-lived and intangible assets, share-based compensation, defined benefit pension plans, and income taxes.

**Disclosures About Fair Value of Financial Instruments.** Estimates of fair value for financial assets and liabilities are based on the framework established in the accounting guidance for fair value measurements. The framework defines fair value, provides guidance for measuring fair value and requires certain disclosures. The framework utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

- Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.
- Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.
- Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

We used the following methods and assumption to estimate the fair value of each class of certain financial instruments for which it is practicable to estimate that value:

- **Cash equivalents and short-term investments:** The carrying amount approximates fair value because of the short maturity of these instruments.
- **Pension assets:** We have level 2 and level 3 pension assets. See Note 5 to our consolidated financial statements.
- **Notes payable:** We estimated the fair value of notes payable based on the current rates offered to us for similar instruments with the same remaining maturities and similar collateral requirements. There was no balance outstanding on notes payable at March 31, 2010 and March 31, 2009.

**Cash and Cash Equivalents.** We consider all cash on-hand and highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. We maintain cash in bank accounts, which, at times, exceed federally insured limits. We have not experienced any losses in such accounts. Cash and cash equivalents held in foreign bank accounts totaled \$792,000 and \$570,000 at March 31, 2010 and 2009, respectively.

**Short-term Investments.** Short-term investments consist of certificates of deposit held-to-maturity that mature within the next twelve months. Based on the short-term nature of these investments, their cost approximates their fair market value. We have determined that short-term investments and cash and cash equivalents are Level 1 inputs within the fair value hierarchy of Accounting Standards Codification (ASC 820), "Fair Value Measurements and Disclosures."

**Accounts Receivable.** We grant credit to our customers in the normal course of business and, generally, do not require collateral or any other security to support amounts due. If necessary, we have an outside party assist us with performing credit and reference checks and establishing credit limits for the customer. Accounts outstanding longer than the contractual payment terms, are considered past due. We carry our accounts receivable at the original invoice amount less an estimate made for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts by considering a number of factors, including the length of time accounts receivables are past due, customer financial condition and ability to pay the obligation, historical and expected credit loss experience, and the condition of the general economy and the industry as a whole. We write off accounts receivable when deemed uncollectible. We record recoveries of accounts receivable previously written off when received. We are not always able to timely anticipate changes in the financial condition of our customers and if circumstances related to these customers deteriorate, our estimates of the recoverability of accounts receivable could be materially affected and we may be required to record additional allowances. Alternatively, if more allowances are provided than are ultimately required, we may reverse a portion of such provisions in future periods based on the actual collection experience. Historically, the accounts receivable balances we have written off have generally been within our expectations. The allowance for doubtful accounts was \$11,000 and \$114,000 at March 31, 2010 and March 31, 2009, respectively.

**Inventories.** Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value). Inventories consist of the following at March 31, 2010 and 2009:

	<u>2010</u>	<u>2009</u>
Raw materials	\$ 158,942	\$ 227,054
Work-in-process	28,935	23,326
Finished goods	153,620	245,371
	<u>\$ 341,497</u>	<u>\$ 495,751</u>

**Property, Plant, and Equipment.** We carry property, plant, and equipment at cost, less accumulated depreciation, which consist of the following at March 31, 2010 and 2009:

	<u>2010</u>	<u>2009</u>
Land	\$ 164,856	\$ 161,829
Building	751,802	737,999
Leasehold improvements	345,495	324,555
Internal use software	307,637	287,960
Equipment	1,198,528	1,206,371
	2,768,318	2,718,714
Less accumulated depreciation	<u>(1,537,547)</u>	<u>(1,317,485)</u>
	<u>\$ 1,230,771</u>	<u>\$ 1,401,229</u>

We provide for depreciation using the straight-line method over useful lives of three to seven years for equipment and 40 years for the building. We charge maintenance and repairs to expense as incurred. We capitalize renewals and improvements and depreciate them over the shorter of their estimated useful service lives or the remaining lease term.

We recognized depreciation expense of approximately \$293,000 and \$290,000 in fiscal years 2010 and 2009, respectively.

**Internal Use Software.** We expense or capitalize internal use software and web site development costs in accordance with ASC 350-40, "Intangibles — Goodwill and Other, Internal-Use Software," and ASC 350-50, "Intangibles — Goodwill and Other, Web Site Development Costs." We capitalized \$17,000 and \$77,000 in fiscal 2010 and 2009, respectively. The net book value of our capitalized software for internal use was \$78,000 and \$136,000 on March 31, 2010 and 2009, respectively.

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

	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Net value</u>
March 31, 2010	\$ 5,472,512	\$ 2,939,417	\$ 2,533,095
March 31, 2009	5,472,512	2,093,864	3,378,648

Estimated annual amortization for these assets for the years ending March 31 is as follows:

2011	\$	843,000
2012		842,000
2013		842,000
2014		4,000
2015 and beyond		2,000
	\$	<u>2,533,000</u>

**Impairment of Long-Lived Assets.** Long-lived assets at March 31, 2010 consist of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that we may not recover the carrying amount of an asset. We measure recoverability of assets held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows we expect to generate by the asset. If we consider such assets impaired, we measure the impairment recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We report assets to be disposed at the lower of the carrying amount or fair value less costs to sell. We completed our impairment analysis and concluded there was no impairment in fiscal years 2010 or 2009.

**Product Warranty.** We warrant our products to be free from defects in material and workmanship under normal use and service for a period of twelve months after the date of sale. Under the terms of these warranties, we repair or replace products we deem defective due to material or workmanship. We recognized warranty expense of \$6,000 and \$8,000 for the years ended March 31, 2010 and 2009, respectively.

**Deferred Rent.** We entered into an 8-year operating lease agreement, effective May 2006, for our corporate facility in Minnesota. As part of the agreement, the landlord provided an incentive of \$280,000 for leasehold improvements. We recorded this incentive as deferred rent and are amortizing it as a reduction in lease expense over the lease term in accordance with ASC 840, "Leases."

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

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated intercompany obligations between us and our foreign subsidiaries. All intercompany balances are revolving in nature and we do not deem any portion of them to be long-term. We recognized foreign currency exchange loss of approximately \$38,000 and \$14,000 for the years ended March 31, 2010 and 2009, respectively.

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

Effective April 1, 2007, we adopted FASB Interpretation No. 48 (FIN 48), "Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement 109," which prescribes a recognition threshold and a measurement attribute for financial statement recognition of tax positions we take or expect to take in a tax return. It is management's responsibility to determine whether it is "more-likely-than-not" that a taxing authority will sustain a tax position upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. At adoption on April 1, 2007, we had no unrecognized tax benefits which needed adjustment. We reviewed all income tax positions taken or that we expect to take

for all open tax years and determined that our income tax positions are appropriately stated and supported for all open years. Accordingly, adoption of FIN 48 did not have a material effect on our consolidated financial statements.

Under our accounting policies we recognize interest and penalties accrued on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. At the adoption date of April 1, 2007, we recognized no interest or penalties related to uncertain tax positions. As of March 31, 2010, we recorded no accrued interest or penalties related to uncertain tax positions.

We recorded income tax expense of \$41,000 and \$115,000 for the years ended March 31, 2010 and 2009, respectively. In fiscal 2009 we recorded an income tax charge of \$67,000 for a settlement we reached with The Netherlands tax authorities for income tax liability for fiscal years 2004 to 2007. We cannot use our U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions.

The fiscal tax years 2006 through 2009 remain open to examination by the Internal Revenue Service and various state taxing jurisdictions to which we are subject. In addition, we are subject to examination by certain foreign taxing authorities for which the fiscal years 2008 through 2009 remain open for examination.

As of March 31, 2010, we have generated approximately \$25 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 the issuance of our common stock in the December 2006 follow-on public offering resulted in an "ownership change" under Section 382. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 may be limited.

**Basic and Diluted Net Loss per Common Share.** We calculate basic per common share amounts by dividing net loss by the weighted-average common shares outstanding. We compute diluted per common share amounts similar to basic per common share amounts except that we increase weighted-average shares outstanding to include additional shares for the assumed exercise of stock options and warrants, if dilutive. Because we had a loss in fiscal 2010 and 2009, diluted shares were the same as basic shares, since inclusion of the options and warrants in the weighted-average outstanding shares would be anti-dilutive. We excluded the following options and warrants outstanding at March 31, 2010 and 2009 to purchase shares of common stock from diluted loss per share as their impact would be anti-dilutive:

Years ended:	<u>Number of Options/Warrants</u>	<u>Range of exercise prices</u>
March 31, 2010	4,104,428	\$ 0.71 – 5.19
March 31, 2009	4,215,428	\$ 1.82 – 5.30

**Advertising Expenses.** Advertising costs are expensed as incurred. We expensed \$189,000 and \$382,000 in fiscal years 2010 and 2009, respectively.

**New Accounting Pronouncements.**

In January 2010, the FASB issued Accounting Standards Update No. 2010-06, "Fair Value Measurements and Disclosures (Topic 820): Improving Disclosures about Fair Value Measurements" (ASU 2010-06). This update provides amendments to Subtopic 820-10 that require new disclosures and clarify existing disclosures. Part of the ASU was effective for our 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 become effective starting our fourth quarter of fiscal 2011. We do not anticipate adoption to have an impact on our financial position or results of operations.

In August 2009, the FASB issued Accounting Standards Update No. 2009-05, "Measuring Liabilities at Fair Value" (ASU 2009-05). This Standards Update provides amendments to ASC Topic 820, "Fair Value Measurements and Disclosure" for the fair value measurement of liabilities when a quoted price in an active market is not available. This ASU was effective for our third quarter of our fiscal 2010 and the adoption did not have an impact on our financial position or results of operations.

In June 2009, the FASB issued SFAS No. 168, "*The FASB Accounting Codification and the Hierarchy of Generally Accepted Accounting Principles.*" SFAS 168 replaced FASB Statement No. 162, "*The Hierarchy of Generally Accepted Accounting Principles,*" and establishes the FASB Accounting Standards Codification™ (Codification) as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with generally accepted accounting principles (GAAP). SFAS 168 was effective for interim and annual periods ending after September 15, 2009. We now use the new Codification when referring to GAAP in our interim financial statements. The adoption of the SFAS 168 changes our references to U.S. GAAP, but does not have an impact on our financial position or results of operations.

In May 2009, the FASB issued ASC 855, "*Subsequent Events.*" This Statement incorporates guidance into accounting literature that was previously addressed only in auditing standards. The statement refers to subsequent events that provide additional evidence about conditions that existed at the balance-sheet date as "recognized subsequent events." Subsequent events which provide evidence about conditions that arose after the balance sheet date but prior to the issuance of the financial statements are referred to as "non-recognized subsequent events." We adopted this standard effective April 1, 2009. See Note 8 to our consolidated financial statements.

## 2. Notes Payable

There were no notes payable outstanding at March 31, 2010 and at March 31, 2009.

On October 30, 2009 we renewed our credit line with Venture Bank. The agreement provides for a credit line of up to \$2 million secured by the assets of our company. We may borrow up to 50% (to a maximum of \$500,000) of the value of our eligible inventory on hand and 80% of the value of our eligible U.S. accounts receivable; provided, however, our total liabilities, inclusive of the amount borrowed, may not exceed our tangible net worth. To be eligible to borrow any amount, we must maintain a minimum tangible net worth of \$5 million. At March 31, 2010 we had no borrowings outstanding under this agreement, but we estimate we had a borrowing capacity of approximately \$0.6 million. Interest on the loan is charged at a per annum rate of the greater of 7.5% or one percentage point over the prime rate (3.25% prime rate on March 31, 2010).

Uroplasty BV, our subsidiary, has an agreement with Rabobank of The Netherlands for a €500,000 (approximately \$673,000) 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 (4.85% base rate on March 31, 2010), subject to a minimum interest rate of 3.5% per annum. At March 31, 2010, we had no borrowings outstanding on this credit line.

## 3. Shareholders' Equity

**Stock Options.** As of March 31, 2010, we had one active plan (2006 Amended Stock and Incentive Plan) for share-based compensation grants. Under the plan, if we have a change in control, all outstanding grants, including those subject to vesting or other performance targets, fully vest immediately. On September 18, 2008 our shareholders amended this plan to increase the number of reserved shares of our common stock for share-based grants to 2,700,000, and as of March 31, 2010, we had remaining 1,497,500 shares available for grant. We generally grant option awards with an exercise price equal to the closing market price of our stock at the date of the grant. We have options outstanding to purchase 1,097,500 shares of common stock granted under this plan. Options granted under this plan generally expire over a period ranging from five to seven years from date of grant and vest at varying rates ranging up to three years.

We have options outstanding to purchase 940,000 shares of common stock, not granted under the 2006 plan, which expire up to ten years from date of grant and vest at varying rates ranging up to five years.

We grant options at the discretion of our directors. Holders may exercise options at a price equal to or greater than the fair market value of our common stock at date of grant. The plans generally provide for the exercise of options during a limited period following termination of employment, death or disability.

There were no proceeds from the exercise of stock options in fiscal years 2010 and 2009.

We recognize share-based compensation expense in the statement of operations based on the fair value of the share-based payment over the requisite service period. We incurred a total of approximately \$415,000 and \$750,000 in share-based compensation expense (inclusive of \$0 and \$60,000, respectively, for grants to consultants) in fiscal year 2010 and 2009, respectively.

We determine the fair value of the option awards using the Black-Scholes option pricing model. We used the following weighted-average assumptions to value the options granted in fiscal 2010 and 2009.

	2010	2009
Expected life, in years	4.82	4.06
Risk-free interest rate	2.74%	3.13%
Expected volatility	94.21%	82.70%
Expected dividend yield	0%	0%

The expected life selected for options granted represents the period of time we expect options to be outstanding based on historical data of option holder exercise and termination behavior for similar grants. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury rate over the expected life at the time of grant. Expected volatility is based upon historical volatility of our stock. We estimate the forfeiture rate for stock awards to range from 0% to 14.5% in fiscal 2010 based on the historical employee turnover rates. The expected life of the options is based on the historical life of previously granted options which are generally held to maturity.

The following table summarizes the activity related to our stock options in fiscal 2009 and 2010:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Fair Value	Aggregate Intrinsic Value	Weighted Average Remaining Life in Years
Balance at March 31, 2008	2,038,100			\$ 1,006,000	
Options granted	237,000		\$ 1.88		
Options surrendered	(140,600)				
Balance at March 31, 2009	2,134,500	\$ 3.93		-	
Options granted	382,500	0.84	0.60		
Options surrendered	(479,500)	4.84			
Balance at March 31, 2010	2,037,500	\$ 3.14		\$ 506,000	4.00
Options exercisable at March 31, 2010	1,764,331	\$ 3.40		\$ 258,000	4.01

As of March 31, 2010 we had approximately \$103,000 of unrecognized compensation cost related to share-based payments projected to be recognized over a weighted-average requisite service period of approximately one year. The total fair value of stock options vested during fiscal 2010 and 2009 was \$567,000 and \$811,000 respectively. No options were exercised during fiscal 2010 and 2009.

In fiscal year 2009, we granted a total of 30,000 restricted shares to certain of our employees. The vesting terms ranged from six to twelve months.

	Number of Shares	Weighted average grant date fair value	Aggregate intrinsic value
Balance at March 31, 2008	-		
Shares granted	30,000	\$ 3.11	
Shares vested	<u>16,000</u>		\$ 49,120
Balance at March 31, 2009	14,000	\$ 3.15	
Shares granted	-	-	
Shares vested	<u>14,000</u>	3.15	44,100
Balance at March 31, 2010	-	\$ -	\$ -

The aggregate intrinsic value represents the total pre-tax value of restricted stock that holders would have received (based on the closing price of our Company's common stock on the grant date) had all restricted stock vested and if we had issued common stock to the holders on the grant date. As of March 31, 2010, all of the restricted shares have fully vested and we had no unrecognized compensation expense related to restricted stock.

**Warrants.** As of March 31, 2010, we had issued and outstanding warrants to purchase an aggregate of 2,066,928 common shares, at a weighted average exercise price of \$3.78. In connection with the equity offerings of April 2005 private placement, August 2006 private placement and December 2006 follow-on offering, we issued five-year warrants to purchase 1,180,928, 764,500, 121,500 common shares, respectively, at exercise prices of \$4.75, \$2.50 and \$2.40 per share, respectively. Warrants to purchase 1,180,928 shares of our common stock, at an exercise price of \$4.75 per share, expired in April 2010.

There were no warrants exercised in fiscal year 2010 or 2009.

**Other Comprehensive Loss.** Other comprehensive loss consists of net loss, accumulated translation adjustment, and pension related items as follows:

	Year Ended March 31,	
	2010	2009
Net loss	\$ (3,203,811)	\$ (3,578,120)
Items of other comprehensive income (loss):		
Translation adjustment	24,643	(554,498)
Pension related	(329,389)	88,868
Comprehensive loss	<u>\$ (3,508,557)</u>	<u>\$ (4,043,750)</u>

Other accumulated comprehensive loss at March 31, 2010 totalled \$495,903 and consists of \$117,745 for accumulated translation adjustment and \$378,158 for accumulated additional pension liability.

4. Commitments and Contingencies

**Royalties.** We received an absolute assignment of a patent relating to the Macroplastique Implantation System, in return for a royalty of 10 British Pounds for each unit sold during the life of the patent. Under the terms of an agreement with some former officers and directors of our company, we pay royalties equal to five percent of the net sales of certain Macroplastique products, subject to a specified monthly minimum of \$4,500. The royalties payable under this agreement will continue until certain patents referenced in the agreement expire in 2012 and 2013. We recognized an aggregate of \$237,000 and \$242,000 of royalty expense, under these agreements in fiscal 2010 and 2009, respectively.

**Purchase Requirements.** In our normal course of business we have commitments, generally for periods of less than one year, to purchase from various vendors finished goods and manufacturing components under issued purchase orders.

**Operating Lease Commitments.** We lease office, warehouse, and production space under operating lease agreements, which include escalating lease payments, and lease various automobiles for our European employees. These leases expire at various times through April 2014. At March 31, 2010, approximate future minimum lease payments in subsequent fiscal years under noncancelable operating leases with an initial term in excess of one year are as follows:

2011	\$	182,000
2012		177,000
2013		160,000
2014		155,000
Thereafter		13,000
	\$	<u>687,000</u>

Total operating lease expenses were \$250,000 and \$263,000 in fiscal 2010 and 2009, respectively.

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

**Product Liability.** The medical device industry is subject to substantial litigation. As a manufacturer of a long-term implantable device, 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 for the products we sell. There can be no assurance, however, that our existing insurance coverage limits are adequate to protect us from any liabilities we might incur.

#### 5. Savings and Retirement Plans

We sponsor various plans for eligible employees in the United States, the United Kingdom (UK), and The Netherlands. Our U.S. retirement savings plan, to which we may make matching discretionary contributions, conforms to Section 401(k) of the Internal Revenue Code, and participation in the plan is available to substantially all U.S. employees. We may also make discretionary contributions ratably to all eligible employees.

We made matching discretionary contributions to the U.S. retirement savings plan of \$105,000 and \$28,000 in fiscal 2010 and 2009, respectively. We suspended further company matching contributions to this plan in January 2010.

Our international subsidiaries have defined benefit retirement plans for eligible employees. These plans provide benefits based on the employee's years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. We froze the U.K. subsidiary's defined benefit plan on December 31, 2004. On March 10, 2005, we established a defined contribution plan for the U.K. subsidiary. As of April 1, 2005 we closed The Netherlands subsidiary's defined benefit retirement plan for new employees and established for them a defined contribution plan. The total contribution expense associated with the defined contribution plans in The Netherlands and the United Kingdom was \$14,000 and \$37,000 for fiscal 2010 and 2009, respectively.

The Netherlands defined benefit pension plan is funded through a guaranteed insurance contract with Swiss Life, an insurance company. The market value of the pension assets is determined as the discounted stream of guaranteed benefit payments at a market rate, increased with the balance of the current account at March 31, 2010. This market rate is assumed to be equal to the discount rate. Therefore, all of the assets as of March 31, 2010 and 2009 are held in Swiss Life insured assets.

As of March 31, 2010 and 2009, we held all the assets of the U.K. defined benefit pension plan in a Deposit Administration Contract with Phoenix Life Limited.

At March 31, 2010 we project the following payments in subsequent fiscal years for the U.K., and The Netherlands defined benefit plans:

2011	\$	293
2012		614
2013		963
2014		1,343
2015		5,363
2016 to 2020		319,655
	\$	<u>328,231</u>

We contributed \$168,000 in fiscal 2010, \$153,000 in fiscal 2009 and expect to contribute approximately \$145,000 in fiscal 2011 to the U.K. and The Netherlands defined benefit pension plans.

The following table summarizes the change in benefit obligations and the change in plan assets for the years ended March 31, 2010 and 2009:

	<u>2010</u>	<u>2009</u>
<b>Changes in benefit obligations:</b>		
Projected benefit obligation, beginning of year	\$ 1,294,389	\$ 1,660,310
Service cost	63,049	63,104
Interest cost	92,823	91,589
Other	(4,831)	(4,216)
Actuarial result	897,250	(187,810)
Foreign currency translation	(12,755)	(328,588)
Projected benefit obligation, end of year	<u>\$ 2,329,925</u>	<u>\$ 1,294,389</u>
<b>Changes in plan assets:</b>		
Plan assets, beginning of year	\$ 1,063,873	\$ 1,333,381
Contributions to plan	168,371	153,385
Benefits paid	-	(4,216)
Management cost	(20,825)	(17,010)
Actual return on assets	512,200	(114,605)
Foreign currency translation	5,269	(287,062)
Plan assets, end of year	<u>\$ 1,728,888</u>	<u>\$ 1,063,873</u>

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

	<u>2010</u>	<u>2009</u>
Unrecognized net prior service benefit	\$ (423,520)	\$ (447,003)
Unrecognized net losses	852,160	514,384
Additional Other Comprehensive Income (gross of deferred taxes)	<u>\$ 428,640</u>	<u>\$ 67,381</u>

Information for our retirement plan in The Netherlands, with projected benefit obligation in excess of the fair value plan assets, at March 31, 2010 and 2009 is as follows:

	2010	2009
Projected benefit obligation	\$1,752,774	\$959,452
Accumulated benefit obligation	1,297,262	717,254
Fair value of plan assets	1,252,104	662,806

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets on March 31, 2010 and 2009, of \$500,670 and \$296,646, respectively, as accrued pension liability.

Information for our retirement plan in the United Kingdom, with projected benefit obligation in excess of the fair value plan assets as at March 31, 2010, and with the fair value of plan assets in excess of the projected benefit obligation at March 31, 2009, is as follows:

	2010	2009
Projected benefit obligation	\$ 577,151	\$ 334,937
Accumulated benefit obligation	577,151	334,937
Fair value of plan assets	476,784	401,067

We have recorded the excess of the projected benefit obligation over the fair value of the plan assets on March 31, 2010 of \$100,367 as accrued pension liability. We have recorded the excess of the fair value of the plan assets over the projected benefit obligation on March 31, 2009 of \$66,130 as prepaid pension asset.

The cost of our defined benefit retirement plans in The Netherlands and United Kingdom include the following components for the years ended March 31, 2010 and 2009:

	2010	2009
Gross service cost, net of employee contribution	\$ 48,103	\$ 48,522
Interest cost	92,823	91,589
Management cost	15,994	17,010
Expected return on assets	5,320	16,875
Amortization	(445)	3,919
Net periodic retirement cost	\$ 161,795	\$ 177,915

Major assumptions used in the above calculations include:

	2010	2009
Discount rate	4.70-5.50%	6.60-6.70%
Expected return on assets	4.70-5.00%	5.00-6.60%
Expected rate of increase in future compensation:		
General	3%	3%
Individual	0-3%	0-3%

The discount rate used is based upon the yields available on high quality corporate bonds with a term that matches the liabilities. The impact of the decrease in discount rate used for March 31, 2010 over 2009 was an increase in the projected benefit obligation and actual return on assets.

**Plan Assets**

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

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

The allocation of pension plan assets for the fiscal years ended March 31, 2010 and 2009 was as follows:

	2010		2009	
	Target Allocation	Actual Allocation	Target Allocation	Actual Allocation
Other Contract (Netherlands Plan)	100%	100%	100%	100%
Deposit Administration Contract (U.K. Plan)	100%	100%	100%	100%

The market value (Vested Benefit Obligation, or VBO) of our Netherlands pension plan assets is determined using the discounted stream of guaranteed benefit payments at a market rate, and other unobservable assumptions such as mortality rates. Accordingly, we have classified the VBO as a Level 3 asset. The market value of the U.K. plan reflects the value of our contributions to the plan and accrued interest credited to the plan assets at the rate specified in the Deposit Administration Contract.

The fair value of the pension plan assets at March 31, 2010, by asset class is as follows:

Asset Class	Total	Quoted Prices in Active Markets for Identical Assets		
		(Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Vested Benefit Obligation (Netherlands Plan)	\$ 1,252,104	\$ -	\$ -	\$ 1,252,104
Deposit Administration Contract (U.K. Plan)	476,784	-	476,784	-

6. Income Taxes

The components of income tax expense for the years ended March 31, 2010 and 2009, consist of the following:

	2010	2009
Income tax provision:		
Current:		
U.S. and State	\$ 24,229	\$ 4,795
Foreign	24,470	73,408
Deferred:		
U.S. and State	-	-
Foreign	(7,320)	36,505
Total income tax expense	\$ 41,379	\$ 114,708

Actual income tax expense differs from statutory federal income tax benefit for the years ended March 31, 2010 and 2009 as follows:

	2010	2009
Statutory federal income tax benefit	\$ (1,139,685)	\$ (1,177,567)
State tax benefit	(87,661)	(81,243)
Foreign tax	(23,058)	(55,997)
Valuation allowance increase	1,208,895	1,252,824
Netherlands tax settlement	-	67,100
Other	82,888	109,591
<b>Total income tax expense</b>	<b>\$ 41,379</b>	<b>\$ 114,708</b>

Deferred taxes as of March 31, 2010 and 2009 consist of the following:

	2010	2009
<b>Deferred tax assets (liabilities):</b>		
Depreciation	\$ (210,748)	\$ (88,405)
Amortization	(923,313)	(1,151,081)
Pension liability	94,425	42,622
Stock based compensation	965,980	825,575
Other reserves and accruals	113,857	86,755
Deferred profit on intercompany sales	154,926	154,926
Deferred rent	41,006	-
Net operating loss carryforwards	9,227,408	8,404,247
	9,463,541	8,274,639
Less valuation allowance	(9,355,011)	(8,205,846)
	<b>\$ 108,530</b>	<b>\$ 68,793</b>

At March 31, 2010, we had U.S. net operating loss (NOL) carryforwards of approximately \$25 million for U.S. income tax purposes, which expire in 2015 through 2028, and NOLs in the U.K. of \$209,000, which we can carry forward indefinitely. U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. In addition, future utilization of NOL carryforwards is subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. We believe that the issuance of our common stock in the December 2006 follow-on public offering resulted in an "ownership change" under Section 382. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 is limited to approximately \$750,000 per year.

Approximately \$1.0 million of our NOL carryforwards resulted from the exercise of stock options. When these loss carryforwards are realized, the corresponding change in valuation allowance will be recorded as additional paid-in capital.

We provide for a valuation allowance when it is more likely than not that we will not realize a portion of the deferred tax assets. We have established a valuation allowance for U.S. and certain foreign deferred tax assets due to the uncertainty that enough income will be generated in those taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such net operating loss carryforwards in the accompanying financial statements. The deferred tax asset increased by \$1,189,000 and \$1,216,000, respectively, in fiscal 2010 and 2009. The related valuation allowance increased by \$1,149,000 and \$1,253,000, respectively, in fiscal 2010 and 2009.

We have provided for U.S. deferred income taxes at March 31, 2010 for the undistributed earnings from our non-U.S. subsidiaries.

Effective April 1, 2007, we adopted FASB Interpretation No. 48 (FIN 48), "Accounting for Uncertainty in Income Taxes — an Interpretation of FASB Statement 109," which prescribes a recognition threshold and a measurement attribute for financial statement recognition of tax positions taken or expected to be taken in a tax return. It is management's responsibility to determine whether it is "more-likely-than-not" that a tax position will be sustained upon examination including resolution of any related appeals or litigation processes, based on the technical merits of the position. At adoption on April 1, 2007, we had no unrecognized tax benefits which needed adjustment. We reviewed all income tax positions taken or that we expect to be taken for all open years and determined that our income tax positions are appropriately stated and supported for all open years and that the adoption of FIN 48 did not have significant effect on our consolidated financial statements.

Under our accounting policies we recognize interest and penalties accrued on unrecognized tax benefits as well as interest received from favorable tax settlements within income tax expense. At the adoption date on April 1, 2007, we recognized no interest or penalties related to uncertain tax positions. As of March 31, 2010, we recorded no accrued interest or penalties related to uncertain tax positions.

The fiscal tax years 2006 through 2009 remain open to examination by the Internal Revenue Service and various state taxing jurisdictions to which we are subject. In addition, we are subject to examination by certain foreign taxing authorities for which the fiscal years 2008 through 2009 remain open for examination.

7. Business Segment Information

ASC 280, "Segment Reporting," establishes disclosure standards for segments of a company based on management's approach to defining operating segments. In accordance with the objective and basic principles of the standard we aggregate our operating segments into one reportable segment.

Information regarding geographic area sales to customers for the fiscal years 2010 and 2009 is as follows:

	<u>United States</u>	<u>United Kingdom</u>	<u>All Other Foreign Countries</u>	<u>Consolidated</u>
Fiscal 2010	\$6,055,978	\$1,577,882	\$4,229,342	\$ 11,863,202
Fiscal 2009	7,980,140	1,906,185	4,855,857	14,742,182

Information regarding geographic area long-lived assets at fiscal years ended 2010 and 2009 is as follows:

	<u>United States</u>	<u>United Kingdom</u>	<u>The Netherlands</u>	<u>Consolidated</u>
March 31, 2010	\$541,005	\$ 3,133	\$ 686,633	\$ 1,230,771
March 31, 2009	704,998	71,110	691,251	1,467,359

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

8. Subsequent Events

We evaluated all subsequent events to ensure that we have included in this Form 10-K appropriate disclosure of events both recognized in the financial statements as of March 31, 2010, and events which occurred subsequent to March 31, 2010 but were not recognized in the financial statements. Subsequent to March 31, 2010 warrants to purchase 528,500 of our common shares were exercised for proceeds to the Company of \$1,309,100. In addition, on May 26, 2010 we exercised the early call provision on the remaining warrants to purchase 375,500 shares of our common stock at an exercise price of \$2.50 per share. Accordingly, any warrants that remain outstanding will expire unless exercised before 6:30 p.m., eastern time, on June 4, 2010.

**BOC \***

**DOCHDR 3**



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**Exhibit 21.0**

**UROPLASTY, INC. AND SUBSIDIARIES**

**Subsidiaries of the Company**

The following are wholly owned subsidiaries of Uroplasty, Inc:

Uroplasty BV  
Hofkamp 2  
6161 DC Geleen  
The Netherlands

Uroplasty, Ltd  
Manchester Business Park  
3000 Aviator Way,  
Manchester, M22 5TG  
United Kingdom



<DOCUMENT>  
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**Exhibit 23.1**

Consent of Independent Registered Accounting Firm

We have issued our report dated May 28, 2010, with respect to the consolidated financial statements and schedule included in the Annual Report of Uroplasty, Inc. on Form 10-K for the year ended March 31, 2010. We hereby consent to the incorporation by reference of said report in the Registration Statements of Uroplasty, Inc. on Forms S-8 (Nos. 333-137410, 333-137409, 333-107110 and 333-30372) and on Forms S-3 (Nos. 333-1491141, 333-128313 and 333-137128) and the Post-Effective Amendment on Form S-3 registration statement (No. 333-133072).

/s/ Grant Thornton LLP

Minneapolis, Minnesota  
May 28, 2010

**BOC \***

**DOCHDR 5**



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**Exhibit 24.1**

**UROPLASTY, INC.**

**Power of Attorney of Director**

Each of the undersigned directors of Uroplasty, Inc., a Minnesota corporation, hereby constitutes and appoints each of David B. Kaysen and Mahedi A. Jiwani, acting individually or jointly, their true and lawful attorneys-in-fact and agents, with full power to act for them and in their name, place and stead, in any and all capacities, to do any and all acts and execute any and all documents which either such attorney and agent may deem necessary or desirable to enable Uroplasty, inc. to comply with the Securities Exchange Act of 1934, as amended, and any rules, regulations and requirements of the Securities and Exchange Commission in respect thereof, in connection with the filing with the Commission of the Annual Report on Form 10-K of Uroplasty, Inc. for the fiscal year ended March 31, 2010, including, without limitation, power and authority to sign the names of the undersigned directors to the Annual Report on Form 10-K and to any instruments and documents filed as part of or in connection with the Form 10-K or any amendments thereto; and the undersigned hereby ratify and confirm all actions taken and documents signed by each said attorney and agent as provided herein.

The undersigned have set their hands this 28th day of May, 2010.

/s/ R. Patrick Maxwell  
R. Patrick Maxwell

/s/ Thomas E. Jamison  
Thomas E. Jamison

/s/ Lee A. Jones  
Lee A. Jones

/s/ James P. Stauner  
James P. Stauner

/s/ Sven A. Wehrwein  
Sven A. Wehrwein



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**Exhibit 31.1**

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David B. Kaysen, certify that:

1. I have reviewed this report on Form 10-K for the year ended March 31, 2010 of Uroplasty, Inc. (the "Registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;

4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and

(d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and

5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

Date: May 28, 2010

By /s/ David B. Kaysen

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David B. Kaysen  
President and Chief Executive Officer



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**Exhibit 31.2**

**CERTIFICATION PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Mahedi A. Jiwani, certify that:

1. I have reviewed this report on Form 10-K for the year ended March 31, 2010 of Uroplasty, Inc. (the "Registrant");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Registrant as of, and for, the periods presented in this report;
4. The Registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the Registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report, based on such evaluation; and
  - (d) disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the Registrant's fourth fiscal quarter in the case of an annual report) that that has materially affected, or is reasonably likely to materially affect, the Registrant's internal control over financial reporting; and
5. The Registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant's auditors and the audit committee of the Registrant's board of directors (or persons performing the equivalent function):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant's ability to record, process, summarize and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant's internal control over financial reporting.

May 28, 2010

Mahedi A. Jiwani  
Vice President, Chief Financial Officer and Treasurer



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**Exhibit 32.1**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Uroplasty, Inc. (the "Company") on Form 10-K for the year ended March 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David B. Kaysen, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: May 28, 2010

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



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**Exhibit 32.2**

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Uroplasty, Inc. (the "Company") on Form 10-K for the year ended March 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mahedi A. Jiwani, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Dated: May 28, 2010

By /s/ Mahedi A. Jiwani  
Mahedi A. Jiwani  
Vice President, Chief Financial Officer and Treasurer