

UROPLASTY INC  
Form 10-K  
May 28, 2010

**Table of Contents**

**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:

**Title of class**

**Name of Exchange on which registered**

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

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

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  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

Edgar Filing: UROPLASTY INC - Form 10-K

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.

---

## TABLE OF CONTENTS

| Item                   | Description   | Page |
|------------------------|---|------|
| <b><u>PART I</u></b>   |   |      |
| <u>1.</u>              | <u>Description of Business</u>  | 4    |
| <u>1A.</u>             | <u>Risk Factors</u>   | 16   |
| <u>2.</u>              | <u>Description of Property</u>  | 24   |
| <u>3.</u>              | <u>Legal Proceedings</u>  | 24   |
| <u>4.</u>              | <u>Reserved</u>   | 24   |
| <b><u>PART II</u></b>  |   |      |
| <u>5.</u>              | <u>Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities</u> | 25   |
| <u>6.</u>              | <u>Selected Financial Data</u>  | 26   |
| <u>7.</u>              | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>                        | 26   |
| <u>7A.</u>             | <u>Quantitative and Qualitative Disclosures About Market Risk</u>   | 34   |
| <u>8.</u>              | <u>Financial Statements and Supplementary Data</u>  | 34   |
| <u>9.</u>              | <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>                         | 34   |
| <u>9A.</u>             | <u>Controls and Procedures</u>  | 34   |
| <u>9B.</u>             | <u>Other Information</u>  | 35   |
| <b><u>PART III</u></b> |   |      |
| <u>10.</u>             | <u>Directors, Executive Officers and Corporate Governance</u>   | 36   |
| <u>11.</u>             | <u>Executive Compensation</u>   | 36   |
| <u>12.</u>             | <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>               | 36   |
| <u>13.</u>             | <u>Certain Relationships and Related Transactions, and Director Independence</u>                                    | 36   |
| <u>14.</u>             | <u>Principal Accountant Fees and Services</u>   | 36   |
| <b><u>PART IV</u></b>  |   |      |
| <u>15.</u>             | <u>Exhibits and Financial Statement Schedules</u>   | 37   |
| <u>EX-13</u>           |   |      |
| <u>EX-21.0</u>         |   |      |
| <u>EX-23.1</u>         |   |      |
| <u>EX-24.1</u>         |   |      |
| <u>EX-31.1</u>         |   |      |
| <u>EX-31.2</u>         |   |      |
| <u>EX-32.1</u>         |   |      |
| <u>EX-32.2</u>         |   |      |

**Table of Contents**

FORWARD LOOKING STATEMENTS

This Form 10-K contains forward-looking statements relating to projections, plans, objectives, estimates, and other statements of future 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.

**Table of Contents**

==

**PART I**

**Item 1. Description of Business**

**Overview**

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our primary focus is on two products: the Urgent PC<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

Edgar Filing: UROPLASTY INC - Form 10-K

\$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-

## **Table of Contents**

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

## **Table of Contents**

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

## **Table of Contents**

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.

## **Table of Contents**

### ***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

## **Table of Contents**

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<sup>™</sup> 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<sup>™</sup> 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.

## **Table of Contents**

*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.

## **Table of Contents**

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

## **Table of Contents**

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® 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® 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® and Toviaz® (both by Pfizer Inc.); Ditropan® (manufactured by Alza Corporation and distributed by Ortho McNeil Pharmaceuticals); Enablex® (Novartis); and Vesicare® (GlaxoSmithKline). These medications treat symptoms of overactive bladder, some by preventing unwanted bladder contractions and others by tightening the bladder or urethra muscles or by relaxing bladder muscles. We believe our Urgent PC 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® distributed by C.R. Bard, Inc.; Deflux® (FDA-approved for vesicoureteral reflux use only) manufactured by Q-Med AB; Durasphere® (FDA-approved for female SUI) manufactured by Carbon Medical Technologies and distributed by Coloplast; and Coaptite® 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.



**Table of Contents**

*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:

- finances, 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.

## **Table of Contents**

### ***European Union and Other Regions***

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

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

We received the CE mark approval for Macroplastique in 1996 for the treatment of male and female stress urinary incontinence and vesicoureteral reflux; for VOX in 2000 for vocal cord rehabilitation 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.

## **Table of Contents**

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. |

**Table of Contents**

**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.

**Table of Contents**

***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

**Table of Contents**

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.

**Table of Contents**

***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

## **Table of Contents**

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

**Table of Contents**

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.

**Table of Contents**

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

Macroplastique is comprised of medical grade, heat-vulcanized polydimethylsiloxane, which results in a solid, flexible 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.

**Table of Contents**

***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

## **Table of Contents**

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**

**Table of Contents**

==

## 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 | Low     | High    |
| 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.

| <b>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b> | <b>Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights</b> | <b>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)</b> |
|--|--|--|
| 1,097,500  | \$ 2.38  | 1,497,500  |

**Equity Compensation Plans  
Approved by Security  
Holders<sup>(1)</sup>**

**Equity Compensation Plans  
Not Approved by Security  
Holders<sup>(2)</sup>**

|              |           |    |      |           |
|--------------|-----------|----|------|-----------|
|              | 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.



**Table of Contents**

**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

## **Table of Contents**

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

**Table of Contents**

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.

## **Table of Contents**

In addition, future utilization of NOL carryforwards are subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. We believe that 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



**Table of Contents**

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

**Table of Contents**

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.

|                             | <b>Years Ended<br/>March 31,<br/>2010</b> | <b>2009</b>   |
|-----------------------------|---|---------------|
| Gross Profit                |   |               |
| 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        |
| <br>                        |   |               |
| Non-GAAP gross profit       | 9,889,852                                 | 12,553,457    |
| <br>                        |   |               |
| Operating Expenses          |   |               |
| 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       |
| <br>                        |   |               |
| Non-GAAP operating expenses | 11,539,555                                | 14,290,427    |
| <br>                        |   |               |
| Operating Loss              |   |               |
| 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       |
| <br>                        |   |               |
| 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

**Table of Contents**

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.

**Table of Contents**

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)<br/>Funded Status at<br/>March 31, 2010</b> | <b>Increase/(Decrease)<br/>Fiscal 2011 pension<br/>expense</b> |
|--|--|--|
| Assumption:  |  |  |
| 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<sup>tm</sup> (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.



**Table of Contents**

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

**Table of Contents**

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.

**Table of Contents**

PART III

**Item 10. Directors, Executive Officers, and Corporate Governance**

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

**Item 11. Executive Compensation**

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

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

The information contained under the heading Principal Shareholders in the Proxy Statement is incorporated herein by reference.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information contained under the heading Certain Relationships and Related Party Transactions, if any, in the Proxy Statement is incorporated herein by reference.

**Item 14. Principal Accountant Fees and Services**

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

**Table of Contents**

## PART IV

**Item 15. Exhibits and Financial Statement Schedules**

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

## 1. Consolidated Financial Statements:

|  | <b>PAGE</b> |
|--|-------------|
| Report of Independent Registered Accounting Firm                       | F-2         |
| Consolidated Balance Sheets  | F-3         |
| Consolidated Statement of Operations                                   | F-5         |
| Consolidated Statements of Shareholders' Equity and Comprehensive Loss | F-6         |
| Consolidated Statements of Cash Flows                                  | F-7         |
| Notes to Consolidated Financial Statements                             | F-8         |

## 2. Financial Statement Schedules:

## Schedule II Valuation and Qualifying Accounts

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

## 3. Exhibits

(a) Exhibits incorporated by reference.

| Number | Description |
|--------|-------------|
|--------|-------------|

Edgar Filing: UROPLASTY INC - Form 10-K

- 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)\*

**Table of Contents**

| 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    |

Edgar Filing: UROPLASTY INC - Form 10-K

|      |   |                    |
|------|---|--------------------|
| 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 |                    |

**Table of Contents****SIGNATURES**

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

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



Sven A. Wehrwein

\* 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.