UROPLASTY INC
Form 10-K
May 28, 2010

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Fiscal Year Ended March 31, 2010

Commission File No. 001-32632

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

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

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

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

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

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES [ ] NO [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

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

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

The aggregate market value of the voting stock held by non-affiliates computed by reference to the price at which the stock was sold or the average bid and asked prices of such stock as of May 21, 2010 was $74,037,000.

As of May 21, 2010 the registrant had 15,310,040 shares of common stock outstanding.

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

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FORWARD LOOKING STATEMENTS

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

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

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

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PART I

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® 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®, a urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency (ISD). Outside of the U.S., our Urgent PC is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence and vesicoureteral reflux.

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

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

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

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

Developments

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

Starting in the second half of fiscal 2009, sales over corresponding year-ago periods of our Urgent PC system declined and continued to do so in fiscal 2010 because of reimbursement-related issues, although sales stabilized at around

$0.9 million to $1 million per quarter in fiscal 2010. We expect Urgent PC sales in the U.S. will likely decline further in fiscal 2011 and we do not expect the sales to return to prior historical levels until after we obtain a unique, listed CPT code and payers create coverage policies that provide adequate reimbursement.

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

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

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

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

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

Market

Neurostimulation Market

Neurostimulation, a form of therapy in which a low-voltage electrical current is used to treat medical conditions affecting parts of the nervous system, has grown dramatically in recent years. FDA-approved neurostimulation devices are currently utilized to treat a range of indications, including voiding dysfunctions, chronic pain, epilepsy, essential tremor, Parkinson s disease, hearing loss and depression. These devices are implanted in the body or used in a non-invasive manner to stimulate different parts of the nervous system, including the spinal cord, sacral nerves and vagus nerve, among other areas. We believe the neurostimulation market represents a significant opportunity for us in the treatment of urinary symptoms often associated with OAB.

Voiding Dysfunction Market

Voiding dysfunctions affect urinary or fecal control and can result in uncontrolled bladder sensations (overactive bladder) or unwanted leakage (urinary or fecal incontinence). OAB is a prevalent and challenging urologic problem affecting an estimated 34 million adult Americans. In 1996, the Agency for Health Care Policy and Research (AHCPR), a division of the Public Health Service, U.S. Department of Health and Human Services, estimated that

urinary incontinence affected about 13 million people in the United States, 85% (11 million) of whom were women. AHCPR estimated the total cost of treating incontinence (management and curative approaches) of all types in the United States at approximately $16 billion per year. Historically, we believe only a small percentage of the patients suffering from these disorders have sought treatment. In

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

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

We believe that over the next several years a number of key demographic and technological factors will accelerate growth in the market for medical devices to treat urinary symptoms often associated with OAB and urinary incontinence. These factors include the following:

Technology advances and patient awareness. Patients often weigh the clinical benefits against the invasiveness of the procedures when choosing a treatment alternative. In recent years, with the publicity associated with new technology and minimally invasive treatment alternatives, we believe the number of patients visiting physicians to seek treatment for voiding dysfunctions has increased. As a result, we believe more patients will choose treatments other than drug therapy, which may have adverse side effects and may not achieve the desired therapeutic effect, or other alternatives, which simply manage their disorder.

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

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

Overactive Bladder

Symptoms

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

Treatment of Symptoms

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

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

Neurostimulation. Normal urinary control is dependent upon properly functioning neural pathways and coordination among the central and peripheral nervous systems, the nerve pathways, the bladder and the

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sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to OAB symptoms. Therapy using neurostimulation incorporates electrical stimulation to target specific neural tissue and jam the pathways transmitting unwanted signals. To alter bladder function, stimulation must be delivered to the sacral nerve plexus, which innervates the bladder and pelvic floor. Neurostimulation for urinary symptoms often associated with OAB is presently conducted through a surgically implanted sacral nerve stimulation device or non-surgical PTNS performed in a physician s office.

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

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

Uroplasty Solution

Urgent PC Non-Surgical Neurostimulation System

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

We believe that the Urgent PC system is the only PTNS device in the United States market for treatment of urinary symptoms often associated with OAB. Components of the Urgent PC system include a hair-width needle electrode, a lead set and an external, handheld, battery-powered stimulator. For each 30-minute office-based therapy session, the physician or other qualified health care provider inserts the needle electrode in the patient s lower leg and connects the electrode to the stimulator. Typically, a patient undergoes 12 consecutive weekly treatment sessions, with follow-up maintenance treatments as required to sustain the therapeutic effect.

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

Urinary Incontinence

Causes of Urinary Incontinence

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

changes associated with aging.

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Types of Urinary Incontinence

There are four types of urinary incontinence:

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

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

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

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

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

Treatment

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

Surgery. In women, stress urinary incontinence can be corrected through surgery with a sling which provides a hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine.

Uroplasty Solution

Macroplastique

Macroplastique is used to treat adult female stress urinary incontinence due to ISD. It is designed to restore the patient s urinary continence immediately following treatment. Macroplastique is a soft-textured, permanent implant injected, under endoscopic visualization, around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone elastomer) implants suspended in a biocompatible excretable carrier gel. We believe our compound is better

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than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

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

Other Uroplasty Products

We also market outside of the U.S. minimally invasive products to address fecal incontinence. Our PTQ™ Implants offer minimally-invasive, soft-textured permanent implant for treatment of fecal incontinence. The PTQ Implants are implanted circumferentially into the submucosa of the anal canal, creating a bulking and supportive effect similar to that of Macroplastique injection for the treatment of stress urinary incontinence. The PTQ is CE marked and currently sold outside the United States in various international markets. The Urgent PC is also CE marked and sold outside of the United States for the treatment of fecal incontinence.

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

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

Uroplasty Strategy

Our goal is to become the leading provider of minimally invasive, office- and outpatient surgical-based solutions for patients who suffer from voiding dysfunctions. We believe that, with our Urgent PC and Macroplastique products, we can increasingly garner the attention of key physicians and distributors to grow our revenue. The key elements of our strategy are to:

Educate physicians and third-party insurance carriers about the benefits of Urgent PC. We believe education of physicians and third-party insurance carriers regarding the benefits of the Urgent PC system is critical to the successful adoption of this system, and to reimbursement for treatments by third-part carriers. To this end, we have conducted clinical studies which we believe will help us with our sales and marketing efforts. We have also submitted the results of these clinical studies with our February 2010 application to the AMA for a unique, listed CPT code. We believe the availability of a unique, listed CPT code will encourage broader use of our Urgent PC.

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

Build patient awareness of office- and outpatient surgical-based solutions. Patients often weigh the quality of life benefits of electing to undergo a surgical procedure against the invasiveness of the procedure. We

intend to continue to expand our marketing efforts to build patient awareness of these treatment alternatives and encourage patients to see physicians. These marketing efforts may include patient-oriented marketing materials for physicians to use to inform patients of the availability and potential benefits of our products. Increasing patient awareness of our treatment alternatives will help physicians build their practices and simultaneously increase sales of our products.

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

Increase market coverage in the United States. We believe that in addition to the international markets where we have had a presence for many years, the United States presents a significant opportunity for growth in sales of our products. In order to grow our business in the United States, we anticipate further increasing our sales and marketing organization, as needed, to support our sales growth.

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

Sales, Distribution and Marketing

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

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

Outside of the United States, we sell our products primarily through a direct sales organization in the United Kingdom and The Netherlands, and in all other markets primarily through distributors. Each of our distributors has a territory-specific distribution agreement, including requirements indicating they may not sell products that compete directly with ours. Collectively, distributors accounted for approximately 28% and 27% of our total net sales for fiscal 2010 and 2009, respectively.

We use clinical studies and scientific community awareness programs to demonstrate the safety and efficacy of our products. This data is important to obtain regulatory approval and to support our sales staff and distributors in securing product reimbursement in their territories. Publications of clinical data in peer-reviewed journals add to the scientific community awareness of our products, including patient indications, treatment technique and expected outcomes. We provide a range of activities designed to support physicians in their clinical evaluation study design, abstract preparation, manuscript creation and review and submission.

Third-Party Reimbursement

In the United States as well as in foreign countries, sales of our products depend in significant part on the availability of reimbursement from third-party payers. In the United States, third-party payers consist of government programs,

such as Medicare, private health insurance plans, managed care organizations and other similar programs. For any product, three factors are critical to reimbursement:

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

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

payment processes and amounts.

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

We believe there are appropriate CPT codes available to describe use of Macroplastique to treat adult female SUI due to ISD in the United States. We will need to foster coverage policies and payer acceptance to increasingly support sales in the United States.

Outside of the United States, government managed health care systems and private insurance control reimbursement for devices and procedures. Reimbursement systems in international markets vary significantly by country. In the European Union, reimbursement decision-making is neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government. Reimbursement for Macroplastique has been successful in multiple international markets where hospitals and physicians have been able to get budgets approved by fund-holder trusts or global hospital budgets.

Manufacturing and Suppliers

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

We manufacture all of our tissue bulking products at our Minnesota facility. Our facility uses dedicated heating, cooling, ventilation and high efficiency particulate air (HEPA) filtration systems to provide cleanroom and other controlled working environments. Our trained technicians perform all critical manufacturing processes in qualified environments according to validated written procedures. We use qualified vendors to sterilize our products using validated methods.

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

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

Competition

The market for voiding dysfunction products is intensely competitive. Competitors offer management and curative treatments, including neurostimulation devices, tissue bulking agents and urethral sling products. Indirect and future competitors include drug companies and medical device firms developing new or improved treatment methods. We believe the principal decision factors among treatment methods include physician and patient acceptance of the treatment method, cost, availability of third-party reimbursement, and marketing and sales coverage. In addition to adequately addressing the decision factors, our ability to compete in this market

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

We believe, the Urgent PC neurostimulation system offers a minimally invasive, office-based treatment alternative to the more invasive implantable Medtronic InterStim® 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 uretheral 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.

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United States

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

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, or total or partial suspension of production;

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

withdrawal of existing approvals; and

criminal prosecution.

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

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

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

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

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

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

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

notices of correction or removal, and recall regulations.

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

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

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

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

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

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

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European Union and Other Regions

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

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

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

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

Patents, Trademarks and Licenses

Our success depends in part on our ability to obtain and maintain patent protection for our products, preserve our trademarks and trade secrets and operate without infringing the proprietary rights of third parties. We seek to protect our technology by filing patent applications for patentable technologies we consider important to the development of our business based on an analysis of the cost of obtaining a patent, the likely scope of protection and the relative benefits of patent protection compared to trade secret protection, among other considerations.

We acquired one granted and several pending patents related to the Urgent PC system when we purchased certain intellectual property assets from CystoMedix in April 2007, and have subsequently filed several related patent applications, some of which are currently pending. In addition, we hold multiple patents covering soft-tissue bulking materials, processes and applications. As of the date of this prospectus, we have seven issued patents in the United States and 17 granted patents in the United Kingdom, Japan, Germany, France, Spain, Italy, Portugal, The Netherlands and Canada. Our patents will expire in the United States at various times between 2011 and 2027 and in other countries between 2013 and 2019.

There can be no assurance that any of our issued patents are of sufficient scope or strength to provide meaningful protection. In addition, there can be no assurance that any of our current or future United States and foreign patents will not be challenged, narrowed, invalidated or circumvented by competitors or others, or that our patents will provide us with any competitive advantage. Any legal proceedings to maintain, defend or enforce our patent rights could be lengthy and costly, with no guarantee of success.

We also seek to protect our trade secrets by requiring employees, consultants, and other parties to sign confidentiality agreements and noncompetition agreements, and by limiting access by outside parties to confidential information. There can be no assurance, however, these measures will prevent the unauthorized disclosure or use of this

information or that others will not be able to independently develop this information.

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

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

Research and Development

We have a research and development program to develop, enhance and evaluate potential new incontinence products for which we incur costs for regulatory submissions, regulatory compliance and clinical research. Our expenditures for clinical research include studies for new applications or indications for existing products, post-approval regulatory compliance and marketing and reimbursement approval by third-party payers. Our expenditures for research and development totaled approximately $1.8 million and $2.6 million for fiscal 2010 and 2009, respectively.

Product Liability

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

Compliance with Environmental Laws

Compliance by us with applicable environmental requirements during fiscal years 2010 and 2009 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

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

Backlog

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

Employees

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

Incorporation and Current Subsidiaries

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