UROPLASTY INC
Form 10-K
June 09, 2008

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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, 2008

Commission File No. 000-20989

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 55413-2820
(Address of principal executive offices)

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

Securities registered under Section 12(g) of the Exchange Act: Common Stock, $.01 par value (Title of class)

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 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. YES [X] NO [ ]

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 (Do not check if a smaller reporting company)	Smaller Reporting Company x

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 27, 2008 was $39,369,522.

As of May 27, 2008 the registrant had 14,932,540 shares of common stock outstanding.

Documents Incorporated By Reference: Portions of our Proxy Statement for our 2008 Annual Meeting of Shareholders (the Proxy Statement), are incorporated by reference in Part III.

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FORWARD LOOKING STATEMENTS

Uroplasty, Inc. may from time to time make written or oral **forward-looking statements,** including our statements contained in this report with the Securities and Exchange Commission and in our reports to stockholders, as well as elsewhere. Forward-looking statements are statements such as those contained in projections, plans, objectives, estimates, statements of future economic performance, and assumptions related to any of the foregoing, and may be identified by the use of forward-looking terminology, such as may, expect, anticipate, estimate, goal, continue comparable terminology. 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, particular, in the Risk Factors discussion contained in the Description of Business section of this report.

We do not undertake and assume no 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 the commercialization of our Urgent PC® system, which we believe is the only FDA-approved minimally invasive, office-based neurostimulation therapy for the treatment of urinary symptoms - urinary urgency, urinary frequency, and urge incontinence often associated with overactive bladder (OAB). We also offer Macroplastique®, a urethral bulking agent for the treatment of adult female stress urinary incontinence. We believe physicians prefer our products because they offer an effective therapy for the patient, can be administered in office-based settings and, to the extent reimbursement is available, provide the physicians a new profitable recurring 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.

The Urgent PC neurostimulation system is a minimally invasive device designed for office-based treatment of urinary symptoms of urge incontinence, urinary urgency and urinary frequency often associated with OAB. The treatment can be administered by the physician or by a qualified office-based staff under the supervision of a physician. The Urgent PC system uses percutaneous tibial nerve stimulation 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.

Macroplastique is a minimally invasive, implantable soft tissue bulking agent for the treatment of adult female stress urinary incontinence. When Macroplastique is injected into tissue around the urethra, it stabilizes and bulks tissues thereby providing the surrounding muscles with increased capability to control the release of urine. 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 female stress urinary incontinence. We began marketing Macroplastique in the United States in 2007.

We are focusing our sales and marketing efforts primarily on urologists, urogynecologists and gynecologists with significant office-based and outpatient surgery-based patient volume. We believe the United States is a significant opportunity for future sales of our products. In order to grow sales in the United States, we established a sales organization, consisting of a direct field sales personnel and independent sales representatives, and a marketing organization to market our products directly to our customers. We intend to develop long-standing relationships with leading physicians treating OAB symptoms and incontinence.

We believe we are the only company offering a minimally invasive, office-based neurostimulation therapy for the treatment of urinary symptoms often associated with OAB. We have intellectual property rights relating to key aspects of our neurostimulation therapy, and we believe our intellectual property portfolio provides a competitive advantage.

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. According to Medtech Insight, the U.S. market for neurostimulation devices is expected to grow from approximately $628 million in 2006 to approximately $2 billion in 2012, representing a compound annual growth rate in excess of 20%. 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

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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 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, of which 85% (11 million) were women. AHCPR estimated the total cost of treating incontinence (management and curative approaches) of all types in the United States as $16 billion. Historically, we believe only a small percentage of the patients suffering from these disorders have sought treatment. In 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 our company is 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 begin to choose treatments other than drug therapy, which may have adverse side effects, 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 cure or treat a voiding dysfunction rather than simply manage it. 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.

Background of 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 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 is an immediate, compelling need to urinate that typically results in an accident before the individual can reach the restroom.

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Treatment of Overactive Bladder 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 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, bladder and 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, the neural tissue affecting bladder activity. Neurostimulation for urinary symptoms often associated with OAB is presently conducted through an implantable sacral nerve stimulation device or non-surgical percutaneous tibial nerve stimulation (PTNS).

> *Surgical.* The sacral nerve stimulation device consists of a surgically implanted lead under the region of the upper buttocks 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 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 for Treatment of Urinary Symptoms Often Associated with Overactive Bladder

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 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 therapeutic session, the physician or other qualified person inserts the needle electrode in the patient s lower leg and connects the electrode to the stimulator. Typically, a patient undergoes 12 treatment sessions at one-week intervals, with follow-up maintenance treatments as required to maintain symptom reduction.

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.

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Background of 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.

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.

Curative Treatment of Urinary Incontinence

Injectable Bulking Agents. Urethral bulking agents are inserted with a needle 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. Urethral bulking agents 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; urethral bulking agents can be implanted in an office or out-patient facility. Additionally, the use of a urethral bulking agent does not preclude the subsequent use of more invasive treatments if required. Furthermore, for patients who have had more invasive treatments, such as

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slings which do not completely resolve their stress urinary incontinence conditions, bulking agents may be used to bring together any remaining urethral opening that may exist.

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 for Urinary Incontinence

Macroplastique

Macroplastique is used to treat 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 placed endoscopically around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone) implants suspended in a biocompatible carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

We have sold Macroplastique for 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

I-Stop™ is a biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. Our I-Stop sling can correct stress urinary incontinence by providing tension-free hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine. We have an exclusive distribution agreement with CL Medical to sell this product in the United Kingdom.

We have minimally invasive products to address fecal incontinence. Our PTQ™ Implants offer a minimally invasive treatment for patients with fecal incontinence. They are soft-textured, permanent implants. For treatment of fecal incontinence, 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 reconstructive and cosmetic plastic surgery under the trade name Bioplastique™ Implants and 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-based neurostimulation solutions for patients who suffer from OAB symptoms. We also plan to market other unique products that can be sold to physicians focused on office-based procedures for the treatment of urinary incontinence. We believe that, with our Urgent PC and

Macroplastique products, we can increasingly garner the attention of key physicians, independent sales representatives and distributors to grow our revenue. The key elements of our strategy are to:

Educate physicians about the benefits of Urgent PC. We believe education of physicians and patients regarding the benefits of the Urgent PC system are critical to the successful adoption of this system. To this end, we initiated in the United States multi-center randomized prospective clinical trial

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comparing the Urgent PC system to the most commonly prescribed pharmaceutical treatment of OAB symptoms. We completed the patient enrollment for this study in late 2007. We believe the results of this and other studies, if successful, will allow us to expand our marketing and clinical sales efforts. These sales and marketing efforts may include physician training and education programs which will emphasize the clinical efficacy and ease of use of our Urgent PC system.

Build patient awareness of office-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 Urgent PC system. Increasing patient awareness of our treatment alternatives will help physicians build their practices and simultaneously increase sales of our products.

Focus on office-based solutions for physicians. We believe our company is uniquely positioned to provide a broad product offering of office-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 and internationally. We believe that in addition to the international market, the United States presents a significant opportunity for future sales of our products. In order to grow our United States business, we have expanded our sales organization, consisting of direct field sales personnel and independent sales representatives, a marketing organization and a reimbursement department to market our products directly to our customers. We anticipate further increasing our sales and marketing organization in the United States, as needed, to support our sales growth. In addition, we intend to expand our European presence by creating new distribution partnerships.

Develop, license or acquire new products. We believe that our office-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 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.

In order to grow our United States business, we have expanded our 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 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,

our distributors accounted for approximately 34% and 52% of total net sales for fiscal 2008 and 2007, respectively. We intend to expand our European presence by creating new distribution partnerships.

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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 surgeons 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 will depend in part on the availability of reimbursement from third-party payors. In the United States, third-party payors 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 payor s policy describing the clinical circumstances under which it will pay for a given treatment; and

payment processes and amounts.

As a relatively new therapy, PTNS using the Urgent PC system has not been assigned a reimbursement code unique to the technology. However, a number of practitioners are using an existing reimbursement code recommended by the American Medical Association that closely describes the PTNS procedure. In addition, Aetna and Blue Cross Blue Shield of Minnesota, Delaware, Northern Virginia, District of Columbia and Maryland have published policies providing coverage for PTNS under an existing reimbursement code. In other states and with other third-party payors, our experience to date indicates that reimbursement coverage is payor-specific. We will need to continue to work with third-party payors 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 codes available to describe use of Macroplastique to treat female SUI due to ISD in the United States. We will need to foster coverage policies and payor 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 manufacturing facility in Minnetonka, Minnesota. The U.S. Food and Drug Administration (FDA) qualified our Minnesota facility in October 2007.

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

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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, marketing and sales coverage and the existence of meaningful patent protection. In addition to adequately addressing the decision factors, our ability to compete in this market will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors affecting our success include our product development and innovation capabilities, clinical study results, ability to obtain required regulatory approvals, ability to protect our proprietary technology, manufacturing and marketing capabilities and ability to attract and retain skilled employees.

We believe, the Urgent PC neurostimulation system may offer a minimally invasive, office-based treatment alternative to the more invasive 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 device, which stimulates the sacral nerve, requires surgical implantation in 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. In addition, Boston Scientific s Bion® Microstimulator, a device implanted with a needle-like instrument to stimulate the pudendal nerve, is CE mark approved for the treatment of urinary urge incontinence and is undergoing clinical studies in the United States.

Many 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. Sometimes, these drugs have unwanted side effects such as dry mouth, vision problems or constipation. Among these medications are Detrol® (Pfizer Inc.), Ditropan® (Alza Corporation), Enablex® (Novartis), Vesicare® (GlaxoSmithKline).

Soft-tissue injectable uretheral bulking agents competing directly with Macroplastique both outside and in the United States include FDA-approved Contigen® manufactured by C.R. Bard, Inc.; Zuidex® and Deflux® (Deflux is FDA-approved for vesico-ureteric reflux use only) manufactured by Q-Med AB; Durasphere® (FDA-approved for female SUI) manufactured by Carbon Medical Technologies; and Coaptite® manufactured by BioForm, Inc. and distributed by Boston Scientific. Macroplastique is a synthetic material that 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. The silicone-elastomer material has been studied for over 50 years in medical use for such urological applications as artificial urinary sphincters, penile implants, stents and catheters.

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

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will continue to conduct research, seek patent protection and establish arrangements for commercializing products. These products may compete directly with any products that we may offer in the future.

Government Regulation

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

United States

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

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, or total or partial suspension of production;

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

withdrawal of existing approvals; and

criminal prosecution.

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

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

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

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

European Union and Other Regions

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

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

We received the CE mark approval for Macroplastique in 1996 for the treatment of male and female stress urinary incontinence and vesicoureteral reflux; for VOX in 2000 for vocal cord rehabilitation applications; for PTQ in 2002 for the treatment of fecal incontinence; and for Bioplastique in 1996 for dermal augmentation applications. 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. The I-Stop sling received the CE mark approval in July 2002.

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 approval where required for us to sell our products in the country. 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 we filed several related patent applications in 2006 and 2007, which are currently pending. In addition, we hold multiple patents covering tissue bulking materials, processes and applications. As of the date of this prospectus, we have four issued patents in the United States and 20 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 2016 and in other countries between 2009 and 2017. There can be no assurance any of our issued patents are of sufficient scope or strength to provide

meaningful protection of our products. In addition, there can be no assurance any current or future United States and foreign patents of ours 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.

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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 PC trademark in April 2007 from CystoMedix. We have registered Macroplastique, VOX, PTQ and Bioplastique as trademarks with the U.S. Patent and Trademark Office. In addition, Macroplastique is registered throughout the European Union. CL Medical has licensed its non-registered trademark for the I-Stop sling to us for use in the United Kingdom for purposes of exercising our rights under our agreement with CL Medical.

We have certain royalty agreements under which we pay royalties on sales of Macroplastique, Bioplastique 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. This program incurs costs for regulatory submissions, regulatory compliance and clinical research. Clinical research includes studies for new applications or indications for existing products, post-approval regulatory and marketing and reimbursement approval by third-party payors. Our expenditures for research and development totaled approximately $1.8 million and $2.3 million for fiscal 2008 and 2007, respectively. None of these costs were borne directly by our customers.

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 five million dollars of worldwide product liability insurance. There can be no assurance; however, our existing insurance coverage limits are adequate to protect us from any 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 2008 and 2007 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

We had two customers, accounting for approximately 7% and 6% of our net sales in fiscal 2008. During fiscal 2007, the same two customers each accounted for approximately 10% of our net sales.

Employees

As of March 31, 2008, we had 63 employees, of which 60 were full-time and 3 were part-time. No employee has a collective bargaining agreement with us. 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.

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

Uroplasty BV	Incorporated in The Netherlands, distributes the Urgent PC, Macroplastique, Bioplastique, 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, Bioplastique, PTQ Implants, all of their accessories, and wound care products in the United Kingdom and Ireland. Also distributes the I-Stop in the United Kingdom. Products are sold primarily through a direct sales organization.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below and all other information contained in this Annual Report on Form 10-K before purchasing our common stock. If the following risks actually occur, our business, financial condition and results of operations could be seriously harmed, the price of our common stock could decline and you could lose part or all of your investment.

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, 2008, we had an accumulated deficit of approximately $20 million primarily as a result 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 to increase 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 for our products and successfully expand our business in the U.S., which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

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 a nationwide network of independent sales representatives and a marketing organization to market our products directly and support our distributor organizations. We anticipate continuing to expand our sales and marketing organization, as needed to support our growth. We have and will continue to incur significant continued and additional expenses to support this organization. We may not be able to recruit, train, motivate or retain qualified sales and marketing personnel or independent sales representatives. Our ability to increase product sales in the U.S. will largely depend upon our ability to develop and maintain the sales organization. Outside of the United States and United Kingdom, we sell our products in foreign markets primarily 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 existing and additional distributors. 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 expand our distribution channels or to recruit, retain and motivate qualified personnel could have a material adverse effect on our product sales and revenues.

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

Our success depends on the