UROPLASTY INC
Form 10-K
June 04, 2009

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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, 2009

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 55413-2820
(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 AlterNext (fka The American Stock Exchange)

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 (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 20, 2009 was $10,711,546.

As of May 20, 2009 the registrant had 14,916,540 shares of common stock outstanding.

Documents Incorporated By Reference: Portions of our Proxy Statement for our 2009 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 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 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.

We offer the 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 have intellectual property rights relating to key aspects of our neurostimulation therapy, and we believe our intellectual property portfolio provides us a competitive advantage.

The Urgent PC treatments 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 (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 also offer Macroplastique®, a minimally invasive, implantable soft tissue urethral 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, 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 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.

In fiscal year 2009, sales of our Urgent PC declined mainly due to reimbursement-related issues for Urgent PC treatments in the U.S. The American Medical Association has advised the medical community that their previously recommended listed CPT code for reimbursement of Urgent PC treatments be replaced with an unlisted code. As a result, some third-party insurance carriers are now denying reimbursement while certain other carriers are reassessing their coverage and reimbursement policies for Urgent PC treatments. However, many other third party payors, under a published positive coverage policy or on a case-by-case basis, continue to provide reimbursement for Urgent PC treatments. We are working with third party payors to clarify the reimbursement process and have undertaken additional clinical studies that we anticipate may assist us in obtaining a specific listed CPT code for PTNS that will encourage broader use of our Urgent PC.

We specifically increased our emphasis on sales of our Macroplastique product in the United States during the second half of fiscal 2009, and particularly in the quarter ended March 31, 2009. We 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. We anticipate increased sales of this product in fiscal 2010.

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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 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.

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

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, the bladder and the 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 an implantable sacral nerve stimulation device or non-surgical PTNS.

Surgical. Direct sacral nerve stimulation devices consist 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 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 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

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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 person 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.

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.

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Curative Treatment of Urinary Incontinence

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 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 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 elastomrer) implants suspended in a biocompatible excretable carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

We have sold Macroplastique for 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 have 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, independent sales representatives 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 are conducting clinical studies in the United States. We believe

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the results of these clinical studies, if successful, will allow us to expand our marketing and sales efforts, and may assist us in obtaining a specific listed CPT code for PTNS that 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 a decade, because it was introduced for sale in the United States in 2007, it is not yet well known and sales are just beginning to accumulate. We believe Mcroplastique 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. In fiscal 2009 we 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.

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.

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 and internationally. We believe that in addition to the international markets, 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. 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- 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 27% and 34% of our

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total net sales for fiscal 2009 and 2008, respectively. We intend to expand our European presence by creating new distribution partnerships.

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 depends in significant 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. The American Medical Association has advised the medical community that their previously recommended listed CPT code for reimbursement of Urgent PC treatments be replaced with an unlisted code. As a result, some third-party insurance carriers are now denying reimbursement while certain other carriers are reassessing their coverage and reimbursement policies for Urgent PC treatments. However, many other third party payors, under a published positive coverage policy or on a case-by-case basis, continue to provide reimbursement for Urgent PC treatments. We are working with third party payors to clarify the reimbursement process and have undertaken additional clinical studies that we anticipate may assist us in obtaining a specific listed CPT code for PTNS that will encourage broader use of our Urgent PC. We do not however, anticipate obtaining a specific listed CPT code in fiscal 2010. 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 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 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 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

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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, 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 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 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. 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) and Vesicare® (GlaxoSmithKline).

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. 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

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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 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;

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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.

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 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

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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.

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

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. 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 $2.6 million and $1.8 million for fiscal 2009 and 2008, 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 $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 2009 and 2008 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During fiscal 2009 or 2008, none of our customers accounted for 10% or more of our net sales.

Backlog

We did not have significant backlog at fiscal yearend 2009 or 2008. We process customer orders generally within one or two days of receipt of the order.

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Employees

As of March 31, 2009, we had 68 employees, of which 64 were full-time and 4 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.

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

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

Item 1A. Risk Factors

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, 2009, we had an accumulated deficit of approximately $23 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 during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability achieve widespread market acceptance and third party reimbursement for our products and successfully expand our business in the U.S., which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

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

Our success depends on the availability of reimbursement for the cost of our products from third-party payors, such as government health authorities, private health insurance plans and managed care organizations. There is no uniform policy for reimbursement in the United States and foreign countries. As a relatively new therapy, PTNS using the Urgent PC system has not been assigned a reimbursement code unique to the technology. This affects the consistency

and speed of reimbursement by payors and thus the willingness of practitioners to utilize our Urgent PC system. Overall, our experience to date indicates that reimbursement coverage is payor-specific. Changes in the extent or type of coverage or a reduction in reimbursement rates or all third-party reimbursement programs may cause a decline in purchases of our products, which would materially adversely affect the market for our products. Alternatively, we might respond to reduced reimbursement rates by reducing the prices of our products, which could also reduce our revenues.

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Further, the American Medical Association has advised the medical community that their previously recommended listed CPT code for reimbursement of Urgent PC treatments be replaced with an unlisted code. As a result, some third-party insurance carriers are now denying reimbursement while certain other carriers are reassessing their coverage and reimbursement policies for Urgent PC treatments. This caused a decline in our Urgent PC sales in the U.S. in fiscal 2009, and we expect that we will not be able to return to significant sales growth or return to our historic sales level until a new listed CPT code is assigned and adequate reimbursement provided. We are working with third party payors to clarify the reimbursement process and have undertaken additional clinical studies that we anticipate may assist us in obtaining a specific listed CPT code for PTNS that will encourage broader use of our Urgent PC. 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 cannot assure you that our efforts to secure a specific listed CPT code for PTNS will be successful, or even if successful, third-party payers will provide or continue to provide coverage and reimbursement, or reimburse the providers an amount sufficient to cover their costs and expenses.

We are unable to predict how quickly or how broadly the market will accept our products. If demand for our products fails to develop as we expect, our revenues will decline or we may be unable to increase our revenues and be profitable.

Our failure to achieve sufficient market acceptance of our products in the U.S. will limit our ability to generate revenue and be profitable. Many of our competitors products have available better and more predictable third-party reimbursement, a feature our competitors stress when competing with us. Market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefits, cost-effectiveness and third party reimbursement of our products compared to products or treatment options of our competitors, and to train physicians in the proper application of our products. We cannot assure you that we will be successful in educating the marketplace about the benefits of using our products. Even if customers accept our products, this acceptance may not translate into sales if our competitors have developed similar products that our customers prefer. Furthermore, if our products do not achieve increasing market acceptance in the U.S. and internationally, our revenues will decline or we may be unable to increase our revenues and 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.

The size and resources of our competitors may allow them to compete more effectively than we can, which could adversely affect our potential profitability.

Our products compete against similar medical devices and other treatment methods, including drugs, for treating voiding dysfunctions. Many of our competitors have significantly greater financial, research and development, manufacturing and marketing resources than we have. Our competitors could use these resources to develop or

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acquire products that are safer, more effective, less invasive, less expensive or more readily accepted than our products. Their products could make our technology and products obsolete or noncompetitive. Our competitors could also devote greater resources to the marketing and sale of their products and adopt more aggressive pricing policies than we can. If we are not able to compete effectively, then we may not be profitable.

We are primarily dependent on sales of two product lines and our business may suffer if sales of these product lines decline.

Currently, we are primarily dependent on sales of our Urgent PC system and Macroplastique product. In fiscal 2009, sales of our Urgent PC system and Macroplastique accounted for approximately 51% and 36%, respectively, of our total net sales. In fiscal 2008, these products accounted for 46% and 37%, respectively, of our total net sales. If demand for our two product lines decline, our revenues and business prospects may suffer.

We may require additional financing in the future which may not be available to us when required, or may be available only on unfavorable terms.

Our future liquidity and capital requirements will depend on numerous factors including: the timing and cost involved in manufacturing scale-up and in expanding our sales, marketing and distribution capabilities in the United States markets; the cost and effectiveness of our marketing and sales efforts with respect to our existing products in international markets; the effect of competing technologies and market, reimbursement and regulatory developments; and the cost involved in protecting our proprietary rights. Because we have yet to achieve profitability and generate positive cash flows, we may need to raise additional financing to support our operations and planned growth activities in the future. Any equity financing could substantially dilute your equity interests in our company and any debt financing could impose significant financial and operational restrictions on us. There can be no guarantee that we will be successful, as we currently have no committed sources of, or other arrangements with respect to, additional equity or debt financing. We cannot assure you that we will obtain additional financing on acceptable terms, or at all.

Our products and facilities are subject to extensive regulation, with which compliance is costly and which exposes us to penalties for non-compliance.

The production and marketing of our products and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the testing, marketing and pre-market review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labelling and record keeping procedures. We are required to obtain regulatory approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot assure that any of our products will be approved or continue to be approved for sale. Any failure to obtain or retain regulatory approvals or clearances could prevent us from successfully marketing our products, which could adversely affect our business and results of operations. Our failure to comply with applicable regulatory requirements could result in governmental agencies:

imposing fines and penalties on us;

preventing us from manufacturing or selling our products;

bringing civil or criminal charges against us;

delaying the introduction of our new products into the market;

enforcing operating restrictions;

recalling or seizing our products; or

withdrawing or denying approvals or clearances for our products.

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If any or all of the foregoing were to occur, we may not be able to meet the demands of our customers and our customers may cancel orders or purchase products from our competitors, which could adversely affect our business and results of operations.

Even if we receive regulatory approval or clearance of a product, the approval or clearance could limit the uses for which we may label and promote the product, which may limit the market for our products. Further, for a marketed product, its manufacturer and manufacturing facilities are subject to periodic reviews and inspections by FDA and foreign regulatory authorities. Subsequent discovery of problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market or other enforcement actions. In addition, regulatory agencies may not agree with the extent or speed of corrective actions relating to product or manufacturing problems.

If additional regulatory requirements are implemented in the foreign countries in which we sell our products, the cost of developing or selling our products may increase. In addition, we may rely on our distributors outside the United States in seeking regulatory approval to market our devices in particular countries. To the extent we do so, we are dependent on persons outside of our direct control to make regulatory submissions and secure approvals, and we do or will not have direct access to health care agencies in those markets to ensure timely regulatory approvals or prompt resolution of regulatory or compliance matters. If our distributors fail to obtain the required approvals or do not do so in a timely manner, our net sales from our international operations and our results of operations may be adversely affected.

In addition, our business and properties are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage, and disposal of hazardous substances, wastes, and other regulated materials. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and results of operations.

The marketing of our products requires a significant amount of time and expense and we may not have the resources to successfully market our products, which would adversely affect our business and results of operations.

The marketing of our products requires a significant amount of time and expense in order to identify the physicians who may use our products, invest in training and education and employ a sales force that is large enough to interact with the targeted physicians. The ease and predictability of third-party reimbursement significantly impacts the success of our marketing activities. We may not have adequate resources to market our products successfully against larger competitors who have more resources than we do. If we cannot market our products successfully, our business and results of operations would be adversely affected.

If third parties claim that we infringe upon their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling the affected product.

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. We face the risk of claims that we have infringed on third parties intellectual property rights. Our efforts to identify and avoid infringing on third parties intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

be expensive and time consuming to defend;

result in us being required to pay significant damages to third parties;

cause us to cease making or selling products that incorporate the challenged intellectual property;

require us to redesign, reengineer or rebrand our products, if feasible;

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require us to enter into royalty or licensing agreements in order to obtain the right to use a third party s intellectual property, which agreements may not be available on terms acceptable to us or at all;

divert the attention of our management; or

result in our customers or potential customers deferring or limiting their purchases or use of the affected products until resolution of the litigation.

In addition, new patents obtained by our competitors could threaten a product s continued life in the market even after it has already been introduced.

If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively and we may not be profitable.

Our success depends in part on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patents and patent applications if issued may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us. As a result, we may not be able to compete effectively.

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

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

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

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

products are used incorrectly by our customers, injury may result and this could give rise to product liability claims against us. Any losses that we may suffer from any liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our products, may divert management s attention from other matters and may have a negative impact on our business and our results of operations.

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The loss or interruption of materials from any of our key suppliers could slow down the manufacture of our products, which would limit our ability to generate sales and revenues.

We currently purchase several key materials used in our products from single source suppliers, including the finished products for our Urgent PC system. Our reliance on a limited number of suppliers subjects us to several risks, including an inability to obtain an adequate supply of required materials, price increases, untimely delivery and difficulties in qualifying alternative suppliers. We cannot be sure that acceptable alternative arrangements could be made on a timely basis. Additionally, the qualification of materials and processes as a result of a supplier change could be deemed as unacceptable to regulatory authorities and cause delays and increased costs due to additional test requirements. A significant interruption in the supply of materials, for any reason, could delay the manufacture and sale of our products, which would limit our ability to generate revenues.

If we are not able to maintain sufficient quality controls, regulatory approvals by the European Union, Canada, the FDA or other relevant authorities of our products could be delayed or denied and our sales and revenues will suffer.

The FDA, European Union, Canada or other related authorities could stop or delay approval of production of products if our manufacturing facilities do not comply with applicable manufacturing requirements. The FDA s Quality System Regulations impose extensive testing, control, documentation and other quality assurance requirements. Canada and the European Union also impose requirements on quality systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Further, our suppliers are also subject to these regulatory requirements. Failure by any of our suppliers or us to comply with these requirements could prevent us from obtaining or retaining approval for and marketing of our products. We cannot assure you that our suppliers or our manufacturing facilities will comply with applicable regulatory requirements on a timely basis or at all.

Even with approval to market our products in the European Union, Canada the United States and other countries, we must continue to comply with relevant manufacturing and distribution requirements. If violations of applicable requirements are noted during periodic inspections of our manufacturing facilities, we may not be able to continue to market our products and our revenues could be materially adversely affected.

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

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

Any product candidate we license or acquire may require additional development efforts prior to sale, including clinical testing and approval by the FDA and other regulatory bodies. Product candidates may fail to receive or experience a significant delay in receiving the necessary approvals. In addition, we cannot assure you that any approved products that we acquire or license will be manufactured economically, successfully commercialized or widely accepted in the marketplace. Other companies, including those with greater financial, marketing and sales resources, may compete with us for the acquisition or license of product candidates or approved products. We may not be able to acquire or license the right to other products on terms that we find acceptable, or at all.

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

we may be unable to integrate the acquired business or products successfully and realize anticipated economic, operational and other benefits in a timely manner; and

the acquisition may disrupt our ongoing business, distract our management and divert our resources.

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If physicians do not recommend and endorse our products, our sales may decline or we may be unable to increase our sales and profits.

In order for us to sell our products, physicians must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from physicians. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy, cost-effectiveness and reimburseability of our products compared to products of our competitors, and on training physicians in the proper application of our products. If we are not successful in obtaining the recommendations or endorsements of physicians for our products, our sales may decline or we may be unable to increase our sales and profits.

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

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

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

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

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

Macroplastique is comprised of medical grade, heat-vulcanized polydimethylsiloxane, which results in a solid, flexible silicone elastomer. In the early 1990 s, the United States silicone gel breast implant industry became the subject of significant controversies surrounding the possible effects upon the human body of the use of semi-liquid silicone gel in breast implants, resulting in product liability litigation and leading to the bankruptcy of several companies, including our former parent, Bioplasty, Inc. We use only medical grade solid silicone material in our tissue bulking products and not semi-liquid silicone gel, as was used in breast implants. Negative publicity regarding the use of silicone materials in our products or in other medical devices could have a significant adverse affect on the overall acceptance of our products. We cannot assure you that the use of solid silicone in medical devices implanted in the human body by us and others will not result in negative publicity.

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The risks inherent in operating internationally and the risks of selling and shipping our products and of purchasing our components and products internationally may adversely impact our net sales, results of operations and financial condition.

We still derive a substantial portion of our net sales from customers and operations in international markets. We expect non-United States sales to continue to represent a significant portion of our revenues until we achieve sufficient market acceptance from United States customers of the already FDA-approved products. The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and exposes us to penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities. In addition, many of the countries in which we sell our products are, to some degree, subject to political, economic and/or social instability. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions.

These risks include:

the imposition of additional U.S. and foreign governmental controls or regulations;

the imposition of costly and lengthy new export licensing requirements;

the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;

political and economic instability;

fluctuations in the value of the U.S. dollar relative to foreign currencies;

a shortage of high-quality sales people and distributors;

loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;

changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

the imposition of new trade restrictions;

the imposition of restrictions on the activities of foreign agents, representatives and distributors;

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

difficulties in enforcing or defending intellectual property rights; and

exposure to different legal and political standards due to our conducting business in approximately 40 countries.

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We cannot assure you that one or more of these factors will not harm our business. Any material decrease in our international sales would adversely impact our net sales, results of operations and financial condition. Our international sales are predominately in Europe. In Europe, health care regulation and reimbursement for medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries.

Fluctuations in foreign exchange rates could negatively impact our results of operations.

Because our international sales are denominated primarily in euros, currency fluctuations in countries where we do business may render our products less price competitive than those of competing companies whose sales are denominated in weaker currencies. We report our financial results in U.S. dollars, and fluctuations in the value of either the dollar or the currencies in which we transact business can have a negative impact on our results of operations and financial condition. Consequently, we have exposure to foreign currency exchange risks. We do not hedge any of our foreign currency risk.

Proposals to modify the health care system in the U.S. or other countries could affect the pricing of our products. If we cannot sell our products at the prices we plan to, our margins and profitability could be adversely affected.

Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reform proposals. We cannot predict whether these reform proposals will be adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in government programs such as Medicare could adversely affect the pricing of our products.

Like the United States, foreign countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates. Any reduction in reimbursement rates under United States or foreign health care programs could negatively affect the pricing of our products. If we are not able to charge a sufficient amount for our products, our margins and our profitability will be adversely affected.

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

Our future success depends, in large part, on the continued service of our senior management. We have no key person insurance with respect to any of our senior managers, and any loss or interruption of their services could significantly reduce our ability to effectively manage our operations and implement our strategy. Also, we depend on the continued service of key managerial, scientific, sales and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. We compete for such personnel with other companies, academic institutions, government entities and other organizations. Any loss or interruption of the services of our other key personnel could also significantly reduce our ability to effectively manage our operations and meet our strategic objectives because we cannot assure you that we would be able to find an appropriate replacement should the need arise.

We also compete for experienced medical device sales personnel. If we are unable to hire and retain qualified sales personnel, our sales could be negatively impacted.

You may be unable to sell your investment.

There is only a limited trading market for our common stock, which is quoted on the NYSE AlterNext. Transactions in our common stock may lack the volume, liquidity and orderliness necessary to maintain a liquid and active trading market. Accordingly, an investor should consider the potential lack of liquidity before investing in our common stock.

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Our stock price may fluctuate and be volatile.

The market price of our common stock may be subject to significant fluctuation due to the following factors, among others:

variations in our quarterly financial results;

developments regarding regulatory clearances or approvals of our products;

market acceptance of our products;

the success of our efforts to acquire or license additional products;

announcements of new products or technologies by us or our competitors;

developments regarding our patents and proprietary rights or those of our competitors;

developments in U.S. or international reimbursement systems;

changes in accounting standards, policies, guidance or interpretations;

sales of substantial amounts of our stock by existing shareholders; and

general economic conditions, including the current economic downturn.

The stock market in recent years has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. These broad market fluctuations may cause the price of our common stock to fall abruptly or remain significantly depressed.

Future sales of our common stock in the public market could lower our share price.

The market price of our common stock could decline due to sales by our existing shareholders of a large number of shares of our common stock or the perception that these sales could occur. These sales could also make it more difficult for us to raise capital through the sale of common stock at a time and price we deem appropriate.

We have a significant number of equity instruments outstanding subject to conversion to our common stock. As of March 31, 2009, we have 2,134,500 shares of our common stock subject to outstanding options and 2,066,928 shares of our common stock subject to outstanding warrants.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We will be evaluating our internal controls systems to allow management to report on, and our independent auditors to attest to, our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement management attestation requirements relating to internal controls and all other aspects of Section 404 by our current March 31, 2010 deadline,

we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, including the SEC. This type of action could adversely affect our financial results or investors confidence in our company and our ability to access capital markets and could cause our stock price to decline. In addition, the controls and procedures that we will implement may not comply with all of the relevant rules and regulations of the SEC. If we fail to develop and maintain effective controls and procedures, we may be unable to provide the required financial information in a timely

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and reliable manner. Further, if we acquire any company in the future, we may incur substantial additional costs to bring the acquired company s systems into compliance with Section 404.

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

Provisions in our articles of incorporation may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our articles of incorporation provide for a staggered board of directors, whereby directors serve for three-year terms, with approximately one third of the directors coming up for reelection each year. Having a staggered board will make it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

We are also subject to the anti-takeover provisions of Section 302A.673 of the Minnesota Business Corporation Act. Under these provisions, if anyone becomes an interested shareholder, we may not enter into a business combination with that person for four years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change of control. For purposes of Section 302A.673, interested shareholder means, generally, someone owning 10% or more of our outstanding voting stock or an affiliate of ours that owned 10% or more of our outstanding voting stock during the past four years, subject to certain exceptions.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Description of Property

In May 2006, we entered into an eight-year lease for an 18,259 square-foot office, warehouse and manufacturing facility in Minnetonka, Minnesota for our corporate headquarters. We own 9,774 square feet of office and warehouse space in Geleen, The Netherlands.

Item 3. Legal Proceedings

There are no material pending legal proceedings other than ordinary routine litigation incidental to our business.

Item 4. Submission of Matters to a Vote of Security Holders

We did not submit any matter to a vote of our security holders during the fourth quarter of our recently completed fiscal year.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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

Our common stock is listed on the NYSE AlterNext (fka The American stock Exchange) under the symbol UPI. The following table sets forth the high and low closing prices for our common stock for our fiscal years ended March 31, 2009 and 2008 as reported on the NYSE AlterNext.

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

Fiscal Year Ended March 31, 2008	Low	High
First Quarter	$ 3.20	$ 5.00
Second Quarter	3.70	4.50
Third Quarter	3.57	4.26
Fourth Quarter	3.00	4.07

As of March 31, 2009, approximately 507 holders held our common stock of record. Registered ownership includes nominees who may hold securities on behalf of multiple beneficial owners.

Securities Authorized for Issuance Under Equity Compensation Plans. The following table provides particular information regarding our equity compensation plans as of March 31, 2009.

Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in the First Column)
1,044,500[1]	$ 3.65	1,835,000[2]

Equity Compensation Plans Approved by Security Holders				
Equity Compensation Plans Not Approved by Security Holders (3)	1,090,000	$	4.20	
Total	2,134,500	$	3.93	1,835,000

(1) Consists of options outstanding under our 2002 Stock Option Plan and 2006 Amended Stock and incentive Plan.

(2) In September 2008 our shareholders amended our 2006 Stock and Incentive Plan to increase the number of our common stock reserved for share-based grants to 2,700,000. As of March 31, 2009, we had remaining 1,835,000 shares available for grant.

(3) The following is a brief description of the various equity compensation plans not approved by our stockholders.

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Our 1995 Stock Option Plan provided for the grant only of non-qualified stock options to our employees, directors, non-employees and consultants, generally exercisable for five years from the date of grant. At March 31, 2009, we had outstanding 80,000 options (all of which are vested), at a weighted average exercise price of $4.50. We froze this plan in May 2006 and may not grant any new options from this plan.

We have also granted options, exercisable over periods ranging from five to ten years from date of grant, from outside of our 1995 Stock Option Plan, generally to our executive officers, directors and employees for their services. At March 31, 2009 we had outstanding 1,010,000 options (all of which are vested), at a weighted average exercise price of $4.17.

Repurchase of Common Stock. We did not repurchase any of our securities during fiscal 2009.

Item 6. Selected Financial Data

Not applicable

Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations

YOU SHOULD READ THIS DISCUSSION OF OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS IN CONJUNCTION WITH, AND WE QUALIFY OUR DISCUSSION IN ITS ENTIRETY BY, THE CONSOLIDATED FINANCIAL STATEMENTS AND NOTES THERETO INCLUDED ELSEWHERE WITHIN THIS ANNUAL REPORT, THE MATERIAL CONTAINED IN THE RISK FACTORS AND DESCRIPTION OF BUSINESS SECTIONS OF THIS ANNUAL REPORT, AND THE CAUTIONARY DISCLOSURE ABOUT FORWARD-LOOKING STATEMENTS AT THE FRONT OF PART I OF THIS ANNUAL REPORT.

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: our Urgent PC® system, which we believe is the only FDA-approved minimally invasive, office-based neurostimulation 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). 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 in place, provide the physicians a new profitable recurring revenue stream. We believe patients prefer our products because they are minimally invasive treatment alternatives and that do not have the side effects associated with pharmaceutical treatment options nor the morbidity associated with surgery.

Our sales growth in fiscal 2009 period over a year ago was influenced by the growing success we had in the first six months of fiscal 2009 with sales of our Urgent PC system in the U.S. In the second half of fiscal 2009, sales in the U.S. of our Urgent PC system declined over the corresponding year-ago period because of reimbursement-related issues. Our results were also impacted by the steadily increasing sales in the U.S. of our Macroplastique product because of our increased sales and marketing focus. With the benefit of increased manufacturing capacity utilization, cost reductions and increase in average selling price of certain products, we have realized increased gross margins. Although we have incurred increased selling and marketing, and research and development expenses, primarily to support the growth in our U.S. business, the increased sales and the improvement in gross margins, together with relatively stable general and administrative expenses, have allowed us to slightly decrease our net loss in fiscal 2009.

In the second half of fiscal 2009, our sales declined over the corresponding year-ago period in part due to reimbursement-related issues for Urgent PC treatments in the U.S. The American Medical Association has advised the medical community that their previously recommended listed CPT code for reimbursement of Urgent PC treatments be replaced with an unlisted code. Some third-party insurance carriers are now reassessing their coverage and reimbursement policies for Urgent PC treatments. However, many other third party payors, under a

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published positive coverage policy or on a case-by-case basis, continue to reimburse for Urgent PC treatments. We are working with third party payors to clarify the reimbursement process and have commissioned additional clinical studies that we anticipate may assist in obtaining a specific listed CPT code for percutaneous tibial nerve stimulation that will encourage broader use of our Urgent PC. In fiscal 2009 we spent approximately $1.3 million and in fiscal 2010 anticipate spending approximately $0.6 million for such clinical studies.

We specifically increased our emphasis on sales of our Macroplastique product in the United States during the second half of fiscal 2009, and particularly in the quarter ended March 31, 2009. We 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. We anticipate increased sales of this product in fiscal 2010.

Critical Accounting Policies

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require us to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing these consolidated financial statements, we have made our best estimates and judgments of certain amounts, giving due consideration to materiality. We believe that of our significant accounting policies, the following are particularly important to the portrayal of our results of operations and financial position. They may require the application of a higher level of judgment by Uroplasty management, and as a result are subject to an inherent degree of uncertainty.

Revenue Recognition. The Securities and Exchange Commission s Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition in Financial Statements, provides guidance on the application of generally accepted accounting principles to selected revenue recognition issues. We believe our revenue recognition policies comply with SAB 104. We recognize revenue upon shipment of product to our distributors and direct customers. We have no customer acceptance provisions or installation obligations. Our sales terms to our distributors and customers provide no right of return outside of our standard warranty, and payment terms consistent with industry standards apply. Sales terms and pricing to our distributors are governed by the respective distribution agreements. Our distributors purchase our products to meet the sales demand of their end-user customers as well as to fulfill their internal requirements associated with the sales process and, if applicable, contractual purchase requirements under the respective distribution agreements. Internal and other requirements include purchases of products for training, demonstration and evaluation purposes, clinical evaluations, product support, establishing inventories, and meeting minimum purchase commitments. As a result, the level of our net sales during any period is not necessarily indicative of our distributors sales to end-user customers during that period, which we estimate are not substantially different than our sales to those distributors in each of the last two years. Our distributors level of inventories of our products, their sales to end-user customers and their internal product requirements may impact our future revenue growth.

Accounts Receivable. We carry our accounts receivable at the original invoice amount less an estimate made for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts based on the customer s financial health, and both historical and expected credit loss experience. We write off our accounts receivable when we deem them uncollectible. We record recoveries of accounts receivable previously written off when received. We are not always able to or timely obtain changes in the financial condition of our customers and if circumstances related to these customers deteriorate, our estimates of the recoverability of accounts receivable could be materially affected and we may be required to record additional allowances. Alternatively, if more allowances are provided than are ultimately required, we may reverse a portion of such provisions in future periods based on the actual collection experience. Historically, the accounts receivable balances we have written off have generally been within our expectations.

Inventories. We state inventories at the lower of cost or market using the first-in, first-out method. We provide lower of cost or market reserves for slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. In assessing the ultimate realization of inventories, we are required to make judgments as to future demand requirements compared with inventory levels. While we expect our sales to grow, a reduction in sales could reduce the demand for our

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products and may require additional inventory reserves. Historically, inventories we have written off have generally been within our expectations.

Foreign Currency Translation/Transactions. The financial statements of our foreign subsidiaries were translated in accordance with the provisions of SFAS No. 52 Foreign Currency Translation. Under this Statement, we translate all assets and liabilities using period-end exchange rates, and we translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders equity. We recognize foreign currency transaction gains and losses in the statement of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates, resulting in an increase in the volatility of our consolidated statements of operations.

Impairment of Long-Lived Assets. Long-lived assets at March 31, 2009 consist of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. We measure the recoverability of assets to be held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If we consider such assets impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We report assets to be disposed of at the lower of the carrying amount or fair value less costs to sell. We did not record any impairment charge in fiscal years 2009 or 2008.

Share-Based Compensation. FASB published SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R). SFAS 123(R) requires that we recognize the compensation cost relating to share-based payment transactions, including grants of employee stock options, in our financial statements. We must measure that cost based on the fair value of the equity or liability instruments issued. SFAS 123(R) covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans.

Defined Benefit Pension Plans. We have a liability attributed to defined benefit pension plans we offered to certain former and current employees prior to April 2005. We pay premiums to an insurance company to fund annuities and are responsible for funding additional annuities based on continued service and future salary increases for these employees pension benefit. The liability is dependent upon numerous factors, assumptions and estimates, and the continued benefit costs we incur may be significantly affected by changes in key actuarial assumptions such as the discount rate, compensation rates, or retirement dates used to determine the projected benefit obligation. Additionally, changes made to the provisions of the plans may impact current and future benefit costs. In accordance with accounting rules, changes in benefit obligations associated with these factors may not be immediately recognized as costs on the income statement, but are recognized in future years over the remaining average service period of plan participants. See Note 5 to our consolidated financial statements for further discussion.

Income Taxes. We recognize deferred tax assets and liabilities for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. We measure deferred tax assets and liabilities using enacted tax rates we expect to apply to taxable income in the years in which we expect to recover or settle those temporary differences. As of March 31, 2009, we have generated approximately $23 million in U.S. net operating loss carryforwards that we cannot use to offset taxable income in foreign jurisdictions. We recognize a valuation allowance when we determine it is more likely than not that we will not realize a portion of the deferred tax asset. We have established a valuation allowance for U.S. and certain foreign deferred tax assets due to the uncertainty that we will generate enough income in those taxing jurisdictions to utilize the assets.

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

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

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Results of Operations

Net Sales. In fiscal 2009, net sales were $14.7 million, representing a $0.9 million or 6% increase compared to net sales of $13.9 million in fiscal 2008. Excluding the impact of fluctuations in foreign currency exchange rates, net sales increased by approximately 8%.

Our fiscal 2009 sales over the corresponding periods in fiscal 2008 increased 41 percent in the first half of the year and declined 20 percent in the second half of the year. We had growing success with sales of our Urgent PC system in the U.S. in the first half of fiscal 2009 over the corresponding period in fiscal 2008, but those sales declined in the second half of fiscal 2009 because of reimbursement-related issues. Partially offsetting this decline was the growing sales of Macroplastique product in the U.S. The second half slowdown in sales outside of the U.S. is attributed primarily to a decline in Macroplastique-related products due to increased competition in foreign countries and an unfavorable impact of foreign currency exchange rates.

Sales to customers in the U.S. in fiscal 2009 totaled $8.0 million, representing a $1.7 million or 27 percent increase compared to $6.3 million in fiscal 2008. We attribute this growth to sales of Macroplastique product and to the sales growth, in the first half of the fiscal year, of the Urgent PC system. Sales of our Macroplastique product, which we launched in late 2007, increased 191% to $1.1 million compared to sales of $0.4 million in fiscal 2008. Sales of our Macroplastique product have steadily increased because of our increased sales and marketing focus in the current fiscal year. Sales of our Urgent PC system increased 17% to $6.8 million compared to $5.8 million in fiscal 2008. However, all the growth in sales of the Urgent PC system occurred in the first half, and, because of reimbursement-related issues, declined in the second half of fiscal 2009.

We anticipate sales of our Macroplastique product in the U.S. to continue to grow in fiscal 2010 as we expect to benefit from our increased sales and marketing effort. We do not expect that we will be able to return to significant sales growth or return to the historic sales level of Urgent PC in the U.S. until a new listed CPT code is assigned and adequate reimbursement provided.

Sales to customers outside the U.S. in fiscal 2009 were $6.8 million, representing a $0.8 million or 11% decrease compared to $7.6 million in fiscal 2008. Excluding the translation impact of fluctuations in foreign currency exchange rates, sales decreased by approximately 8%. In fiscal 2009, the U.S. dollar against our foreign currency denominated sales was weaker in the first half, creating a favorable benefit on translated sales, and was stronger in the second half, creating an unfavorable benefit on translated sales, over corresponding year-ago periods. Our sales increased 7% in the first half, primarily due the favorable impact of fluctuations in currency exchange rates. In the second half, sales declined 28%. About one-half (approximately $0.5 million) of this decline is attributed to the unfavorable impact of fluctuations in exchange rates, with the rest attributed primarily to decline in Macroplastique-related products due to increased competition.

Gross Profit. Gross profit was $12.5 million and $10.9 million for the fiscal years ended March 31, 2009 and 2008, respectively, or 85% and 79% of net sales in the respective periods.

We attribute the higher gross profit percentage in fiscal 2009 mainly to the 4.6 percentage point favorable impact of product mix and cost reductions attributed to our Urgent PC system. In addition, in fiscal 2008 we had incurred $130,000 for rent and lease exit charges due to the discontinuation of manufacturing at our Eindhoven, The Netherlands facility.

General and Administrative Expenses. General and administrative (G&A) expenses decreased from $3.7 million in fiscal 2008 to $3.4 million in fiscal 2009. Included in fiscal 2008 was a $664,000 non-cash charge for share-based employee compensation, compared with a charge of $306,000 in fiscal 2009. Excluding share-based compensation

charges, G&A expenses increased by $95,000.

Research and Development Expenses. Research and development (R&D) expenses increased from $1.8 million in fiscal 2008 to $2.6 million in fiscal 2009. We attribute the increase in spending for fiscal 2009 primarily due to an increase in spending for clinical studies. We have commissioned additional clinical studies that we anticipate may assist us in obtaining the specific listed CPT code that will encourage broader use of our Urgent PC. In fiscal 2009 we spent approximately $1.3 million, compared with $0.4 million in fiscal 2008 on clinical studies, and in fiscal 2010 we anticipate spending of approximately $0.6 million for such clinical studies.

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Selling and Marketing Expenses. Selling and marketing expenses increased from $8.5 million in fiscal 2008 to $9.3 million in fiscal 2009. We attribute the increase to a $397,000 increase in compensation-related costs, primarily as a result of increased salaries, a $229,000 increase in consulting costs to support our efforts to secure reimbursement for Urgent PC treatments in the U.S., and an increase in other costs to support our expanded sales organization and marketing activities.

Amortization of Intangibles. Amortization expenses of intangibles were $846,000 and $844,000 during fiscal 2009 and 2008, respectively. Our amortization expense is attributed primarily to our April 2007 acquisition for $4.7 million certain intellectual property assets related to the Urgent PC system. We are amortizing this acquisition cost over six years.

Other Income (Expense). Other income (expense) includes interest income, interest expense, warrant expense, foreign currency exchange gains and losses and other non-operating costs when incurred. Other income was $159,000 and $160,000 for fiscal 2009 and fiscal 2008, respectively. Interest income decreased from $312,000 in fiscal 2008 to $197,000 in fiscal 2009 because of lower average invested cash balance and decreased interest rates.

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated intercompany obligations between us and our foreign subsidiaries. All intercompany balances are revolving in nature and we do not deem them to be long-term balances. We recognized net foreign currency exchange loss of $14,000 and $118,000 for the years ended March 31, 2009 and 2008, respectively.

Income Tax Expense: We recorded income tax expense of $115,000 and $55,000 for the years ended March 31, 2009 and 2008, respectively. The income tax expense we recorded is attributed primarily to our operations in Netherlands. In fiscal 2009 we recorded an income tax charge of $67,000 for a settlement we reached with the Netherlands tax authorities for income tax liability for fiscal years 2004 to 2007. We cannot use our U.S. net operating loss carry forwards to offset taxable income in foreign jurisdictions.

Non-GAAP Financial Measures. The following table reconciles our financial results calculated in accordance with accounting principles generally accepted in the U.S. (GAAP) to non-GAAP financial measures that exclude non-cash charges for share-based compensation, and depreciation and amortization expenses from gross profit, operating expenses and operating loss. The non-GAAP financial measures used by management and disclosed by us are not a substitute for, or superior to, financial measures and consolidated financial results calculated in accordance with GAAP, and you should carefully evaluate our reconciliations to non-GAAP. We may calculate our non-GAAP financial measures differently from similarly titled measures used by other companies. Therefore, our non-GAAP financial measures may not be comparable to those used by other companies. We have described the reconciliations of each of our non-GAAP financial measures above to the most directly comparable GAAP financial measures.

We use these non-GAAP financial measures, and in particular non-GAAP operating loss, for internal managerial purposes because we believe such measures are one important indicator of the strength and the performance of our business as they provide a link to operating cash flow. We also believe that analysts and investors use such measures to evaluate the overall operating performance of companies in our industry, including as a means of comparing period-to-period results and as a means of evaluating our results with those of other companies.

Our non-GAAP operating loss for fiscal 2009 and 2008 was approximately $1.7 million and $1.8 million, respectively.

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	Years Ended March 31, 2009	2008
Non-GAAP Gross Profit		
GAAP gross profit	$12,458,207	$10,920,676
% of sales	85%	79%
Share-based compensation	42,818	22,531
Depreciation expenses	52,432	54,635
Non-GAAP gross profit	12,553,457	10,997,842
Non-GAAP Operating Expenses		
GAAP operating expenses	16,080,583	14,849,871
Share-based compensation	706,788	1,016,362
Depreciation expenses	237,844	174,384
Amortization expenses	845,524	843,533
Non-GAAP operating expenses	14,290,427	12,815,592
Non-GAAP Operating Loss		
GAAP operating loss	(3,622,376)	(3,929,195)
Share-based compensation	749,606	1,038,893
Depreciation expenses	290,276	229,019
Amortization expenses	845,524	843,533
Non-GAAP operating loss	$(1,736,970)	$(1,817,750)

Liquidity and Capital Resources

Cash Flows. At March 31, 2009, our cash and cash equivalent and short-term investments balances totaled $7.8 million.

At March 31, 2009, we had working capital of approximately $7.8 million. In fiscal 2009, we used $1.4 million of cash in operating activities, compared to $1.8 million of cash used in fiscal 2008. We attribute the decrease in cash used in operating activities primarily to the increase in sales for the year, an improvement in gross profit rate and a reduction in accounts receivable primarily because of a reduction fourth fiscal quarter sales over the corresponding year-ago period, offset partially by a reduction accrued liabilities primarily because of a reduction in management bonuses on lower-than-planned operating financial performance.

In fiscal 2009 we used approximately $200,000 to purchase property, plant and equipment compared with approximately $302,000 in fiscal 2008.

In fiscal 2009 we used cash in financing activities of approximately $456,000 to retire debt, while in fiscal 2008 we generated approximately $5.3 million of cash in financing activities, comprised of approximately $5.4 million we generated from issuance of common stock and exercise of warrants and options.

Sources of Liquidity. In November 2007, we conducted a secondary offering in which we sold 1,466,400 shares of our common stock at price of $3.50 per share, for an aggregate purchase price of approximately $5.1 million. The stock sale proceeds are offset by costs of approximately $526,000, resulting in net proceeds of approximately $4.6 million.

In September 2008 we entered into a one-year business loan agreement with Venture Bank. The agreement provides for a credit line of up to $2 million secured by the assets of our company. We may borrow up to 50% (to a maximum of $500,000) of the value of our eligible inventory on hand and 80% of the value of our eligible U.S. accounts receivable; provided, however, our total liabilities, inclusive of the amount borrowed, may not exceed our tangible net worth. To be eligible to borrow any amount, we must maintain a minimum tangible net worth of $5 million. Interest on the loan is charged at a per annum rate of the greater of 7.5% or

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one percentage point over the prime rate (3.25% prime rate on March 31, 2009). At March 31, 2009, we had no borrowings outstanding on this credit line.

Uroplasty BV, our subsidiary, has an agreement with Rabobank of The Netherlands for a 500,000 (approximately $660,000) credit line secured by our facility in Geleen, The Netherlands. The bank charges interest on the loan at the rate of one percentage point over the Rabobank base interest rate (5.1% base rate on March 31, 2009), subject to a minimum interest rate of 3.5% per annum. At March 31, 2009, we had no borrowings outstanding on this credit line.

We believe we have sufficient liquidity to meet our needs over the next twelve months. However, we may need to raise additional financing to support our operations and planned growth activities in the future as we have yet to achieve profitability and generate positive cash flows. To achieve profitability, we must generate substantially more revenue than we have this year or in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability to achieve widespread market acceptance for our products and successfully expand our business in the U.S., which in turn may be partially dependent upon re-establishing broad reimbursement for our Urgent PC product and successfully demonstrating the superiority of our Macroplastique product to clinicians. We cannot guarantee that we will be entirely successful in either of these pursuits. If we are unable to raise the needed funds, we may need to curtail our operations including product development, clinical studies and sales and marketing activities. This would adversely impact our future business and prospects. Ultimately, we will need to achieve profitability and generate positive cash flows from operations to meet our cash needs and grow our business.

Commitments and Contingencies. We expect to continue to incur significant costs for clinical studies to support our effort to obtain a specific listed CPT code that we anticipate will encourage broader use of our Urgent PC System in the U.S. We expect that in fiscal 2010 we will spend approximately $0.6 million for such clinical studies. We also expect to continue to incur significant expenses to support our U.S. sales and marketing organization, and for regulatory activities.

Under a royalty agreement we pay royalties, in the aggregate, of three to five percent of net sales of Macroplastique, Bioplastique, and PTQ Implants subject to a monthly minimum of $4,500. The royalties payable under this agreement will continue until the patent referenced in the agreement expires in 2010. Under a license agreement for the Macroplastique Implantation System, we pay a royalty of 10 British pounds for each unit sold during the life of the patent.

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

We have a defined benefit pension plan covering seven employees in The Netherlands. We pay premiums to an insurance company to fund annuities for these employees. However, we are responsible for funding additional annuities based on continued service and future salary increases. We closed this defined benefit plan for new employees in April 2005. As of that date, the Dutch subsidiary established a defined contribution plan that now covers new employees. We have a defined benefit pension plan for six former employees of our UK subsidiary. We closed this plan to further accrual for all employees effective December 31, 2004, and, effective March 2005, established a defined contribution plan that now covers new employees.

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The following table presents the sensitivity of our funded status as of March 31, 2009, and fiscal 2010 pension expense to the following changes in key assumptions:

	Increase/(Decrease) Funded Status at March 31, 2009	Increase/(Decrease) Fiscal 2010 pension expense
Assumption:		
Increase in discount rate of 1%	$ 100,000	$ (4,000)
Decrease in discount rate of 1%	(127,000)	4,000
Increase in estimated return on assets of 1%	-	(4,000)
Decrease of estimated return on assets of 1%	-	4,000
Increase in inflation of 1%	(179,000)	29,000
Decrease in inflation of 1%	151,000	(25,000)
Increase in compensation of 1%	(146,000)	31,000
Decrease in compensation of 1%	7,000	(1,000)

In January 2006, we entered into a long-term lease with Liberty Property Limited Partnership for an 18,258 square foot facility for our U.S. headquarters located at 5420 Feltl Road, Minnetonka, Minnesota. The lease effective date was May 1, 2006, has a term of 96 months, requires average annual minimum rent payments of approximately $140,000 and requires payments for operating expenses we estimated at approximately $99,000 over 12 months.

Recent Accounting Pronouncements

In December 2008, the FASB issued FSP FAS 132(R)-1, *Employers Disclosures about Postretirement Benefit Plan Assets* (FSP FAS 132(R)-1). FSP FAS 132(R)-1 provides guidance on an employer s disclosures about plan assets of a defined benefit pension or other postretirement plan. The requirements are effective for fiscal years beginning after December 15, 2009. FSP FAS 132(R)-1 pertains only to the disclosures and does not affect the accounting for defined benefit pensions or other postretirement plans; therefore, we do not anticipate adoption of FSP FAS 132(R)-1 to have an impact on our financial position or results of operations.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets* (FSP FAS 142-3), which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets.* FSP FAS 142-3 is effective for fiscal years beginning after December 15, 2008 and is applied prospectively to intangible assets acquired after the effective date.

In December 2007, the FASB issued SFAS 141(R), *Business Combinations*, which requires the acquiring entity in a business combination to recognize and measure all assets and liabilities assumed in the transaction and any non-controlling interest in the acquiree at fair value as of the acquisition date. SFAS 141(R) also establishes guidance for the measurement of the acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting treatment of pre-acquisition gain and loss contingencies, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer s income tax valuation allowance and deferred taxes. In April 2009, the FASB issued FSP FAS 141(R)-1 *Accounting for Assets Acquired and Liabilities Assumed in a Business Combination That Arise from Contingencies,* which amends and clarifies SFAS 141(R) by establishing a model to account for certain pre-acquisition contingencies. FSP FAS 141(R)-1 addresses issues associated with initial recognition and measurement, subsequent measurement and accounting, and disclosure of assets and liabilities arising from contingencies in a business combination. SFAS 141(R) and FSP FAS 141(R)-1 are

effective for fiscal years beginning after December 15, 2008 and are applied prospectively as of the beginning of the fiscal year in which the statement is applied. Early adoption is not permitted.

In December 2007, the FASB issued SFAS 160, *Noncontrolling Interest in Consolidated Financial Statements An Amendment of ARB 51*, which establishes accounting and reporting standards that require reporting of noncontrolling interests as a component of equity. SFAS 160 also requires that a parent account as equity transactions, changes in ownership interest while it retains its controlling interest. SFAS 160 further

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requires that a parent initially measure at fair value any retained noncontrolling equity investment upon the deconsolidation of a subsidiary. SFAS 160 is effective for fiscal years beginning after December 15, 2008 and is applied prospectively as of the beginning of the fiscal year in which the statement is applied.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value under generally accepted accounting principles, and expands disclosure about fair value measurements. In February 2008, the FASB issued FSP FAS 157-2, *Effective date of FASB Statement No. 157* (FSP FAS 157-2). FSP FAS 157-2 defers the implementation of SFAS No. 157 for certain nonfinancial assets and liabilities. We adopted the required provisions of SFAS No. 157 as of April 1, 2008 and will adopt the provisions of FSP FAS 157-2 on April 1, 2009. The adoption of SFAS 157 did not have an impact on our financial position or results of operations and we do not expect that the adoption of FSP FAS 157-2 to have an impact on our financial position or results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Foreign Currency Risk Due to the global nature of our operations, we are subject to exposures resulting from foreign currency exchange fluctuations in the normal course of business. Our primary exchange rate exposures are with the Euro and the British pound. The direct financial impact of foreign currency exchange includes the effect of translating profits from local currencies to U.S. dollars, the impact of currency fluctuations on the transfer of goods between our operations in the United States and abroad and transaction gains and losses. In addition to the direct financial impact, foreign currency exchange has an indirect financial impact on our results, including the effect on sales volumes within local economies and the impact of any pricing actions taken as a result of foreign exchange rate fluctuations. Because our products are currently manufactured or sourced primarily from the United States, a stronger dollar generally has a negative impact on results from operations outside the United States, while a weaker dollar generally has a positive effect.

Interest Rate Risk Our primary market risk with financial instruments results from fluctuations in interest rates. Our cash is invested in bank deposits, certificate of deposits and money market funds denominated in U.S. dollars, Euros and British pounds. The carrying value of these instruments approximates fair market value. These investments are subject to interest rate risk and their value could be adversely affected by movements in interest rates.

Other Matters Management regularly reviews our business operations, processes and overall organizational structure with the objective of improving our financial performance. As a result of this ongoing process to improve financial performance, we may incur restructuring charges in the future which, if taken, could be material to our financial results.

Item 8. Financial Statements and Supplementary Data

The information contained in Exhibit 13 under the headings Consolidated Statements of Operations, Consolidated Balance Sheets, Consolidated Statements of Shareholders Equity and Comprehensive Loss, Consolidated Statements of Cash Flows, Notes to Consolidated Financial Statements and Report of Independent Registered Public Accounting Firms is incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures. Under the supervision and with the participation of our management, including, our President and Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934 (the Exchange Act). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that the information required to be

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disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, in a manner that allows timely decisions regarding required disclosure.

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

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

Under the supervision and with the participation of our management, including our CEO and CFO, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation under the framework in Internal Control Integrated Framework, our management concluded that our internal control over financial reporting was effective as of March 31, 2009. There were no changes in our internal control over financial reporting during the quarter ended March 31, 2009, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers, and Corporate Governance

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

Item 11. Executive Compensation

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

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

The information contained under the heading Principal Shareholders and Beneficial Ownership of Management in the Proxy Statement is incorporated herein by reference.

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

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

Item 14. Principal Accountant Fees and Services

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

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

1. Consolidated Financial Statements:

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

2. Financial Statement Schedules:

Schedule II Valuation and Qualifying Accounts

	Balance at beginning of fiscal year	Additions charged to costs and expenses	Written off, less recoveries	Effects of foreign currency fluctuations	Balance at end of fiscal year
Allowance for doubtful accounts and sales returns					
Fiscal year ended March 31, 2009	$ 82,000	$ 341,000	$ (245,000)	$(1,000)	$ 177,000
Fiscal year ended March 31, 2008	$ 7,000	$ 146,000	$ (71,000)	$-	$ 82,000
Warranty reserve					
Fiscal year ended March 31, 2009	$ 4,000	$ 8,000	$ (10,000)	$-	$ 2,000
Fiscal year ended March 31, 2008	$ 26,000	$ 12,000	$ (34,000)	$-	$ 4,000

3. Exhibits

(a) Exhibits incorporated by reference.

Number	Description
3.1	Restated Articles of Incorporation of Uroplasty, Inc. (Incorporated by reference to Exhibit 3.1 to Registrant s Registration Statement on Form SB-2 filed October 18, 2007 (File No. 333-146787))
3.2	Amendment to Restated Articles of Incorporation of Uroplasty, Inc. (Incorporated by reference to Exhibit 3.3 to Registrant s Form 8-K filed dated October 25, 2006)
4.1	Form of Stock Certificate representing shares of our Common Stock (Incorporated by reference to Exhibit 3.1 to Registrant s Registration Statement on Form 10SB 12G filed July 10, 1996)

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Number	Description
4.2	Form of Warrant (Incorporated by reference to Exhibit 4.2 to Registrant s Registration Statement on Form SB-2 filed September 14, 2005 (File No. 333-128313))
4.3	Form of Selling Agent s Warrant (Incorporated by reference to Exhibit 4.3 to Registrant s Form SB-2/A 1 filed November 27, 2006 (File No. 333-138267))
10.1	Settlement Agreement and Release dated November 30, 1993 by and between Bioplasty, Inc., Bio-Manufacturing, Inc., Uroplasty, Inc., Arthur A. Beisang, Arthur A. Beisang III, MD and Robert A. Ersek, MD (Incorporated by reference to Exhibit 6.1 to Registrant s Registration Statement on Form 10SB filed July 10, 1996)
10.2	Employment Agreement between Uroplasty, Inc. and Susan Holman dated December 7, 1999. (Incorporated by reference to Exhibit 10.13 to Registrant s Form 10-KSB for the year ended March 31, 2000 filed June 26, 2000)*
10.3	Employment Agreement between Uroplasty, Inc. and Larry Heinemann dated December 7, 1999. (Incorporated by reference to Exhibit 10.14 to Registrant s Form 10-KSB for the year ended March 31, 2000, filed June 26, 2000)*
10.4	Agreement, dated October 14, 1998, by and between Uroplasty, Inc. and Samir M. Henalla (pertaining to Macroplastique Implantation System). (Incorporated by reference to Exhibit 10.15 to Registrant s Form 10-KSB/A for the year ended March 31, 2001, filed March 27, 2002)
10.5	2002 Employee Stock Option Plan (Incorporated by reference to the copy filed as Appendix B to the Proxy Statement filed with the SEC on August 1, 2002)*
10.6	Employment Agreement between Uroplasty, Inc. and Mr. Marc Herregraven dated November 15, 2002. (Incorporated by reference to Exhibit 10.15 to Registrant s Form 10-KSB for the year ended March 31, 2003, filed May 20, 2003)*
10.7	Form of Securities Purchase Agreement dated as of April 21, 2005, by and among Uroplasty, Inc., and the investors identified on the signature pages thereto (Incorporated by reference to Exhibit 10.20 to Registrant s Form 8-K filed dated April 26, 2005)
10.8	Form of Warrant (Incorporated by reference to Exhibit 10.21 to Registrant s Form 8-K filed April 26, 2005)
10.9	Form of Registration Rights Agreement dated as of April 21, 2005, by and among Uroplasty, Inc., and the investors named therein (Incorporated by reference to Exhibit 10.22 to Registrant s From 8-K filed dated April 26, 2005)
10.10	Employment Agreement between Uroplasty, Inc. and Mahedi A. Jiwani dated November 14, 2005 (Incorporated by reference to Exhibit 10.24 to Registrant s Form 10-QSB filed November 14, 2005)*
10.11	Lease Agreement between Uroplasty, Inc. and Liberty Property Limited Partnership dated January 20, 2006 (Incorporated by reference to Exhibit 10.25 to Registrant s Form 8-K filed January 24, 2006)
10.12	Employment Agreement between Uroplasty, Inc. and David B. Kaysen dated May 17, 2006 (Incorporated by reference to Exhibit 10.30 to Registrant s Form 10-KSB filed June 29, 2006)*
10.13	Form of Registration Rights Agreement dated as of August 7, 2006, by and among Uroplasty, Inc., and the investors identified named therein (Incorporated by reference to Exhibit 10.34 to Registrant s Form 8-K filed August 8, 2006)
10.14	Form of Warrant dated August 7, 2006 (Incorporated by reference to Exhibit 10.33 to Registrant s From 8-K filed August 8, 2006)
10.15	

	Form of Purchase Agreement, dated as of March 15, 2007, by and between Uroplasty, Inc. and CystoMedix, Inc. (Incorporated by reference to Exhibit 10.36 to Registrant s Form 8-K filed March 20, 2007
10.16	2006 Amended Stock and Incentive Plan (Incorporated by reference to the copy attached as Appendix A to the Company s Definitive Proxy Statement filed on July 25, 2008)*

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Number	Description
10.17	Business Loan Agreement and related Promissory Note dated September 3, 2008 with Venture Bank (Incorporated by reference to Exhibit 10.23 to Registrant s Form 8-K filed September 4, 2008)
14.1	Revised Code of Ethics titled Code of Business Conduct and Ethics for Directors, Officers and Employees (Incorporated by reference to Exhibit 14.1 to Registrant s Form 8-K filed April 12, 2007)

* Management contract, compensation plan or arrangement

(c) Exhibits filed herewith.

Number	Description
13	Financial Statements
21.0	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm Grant Thornton LLP
31	Certifications by the CEO and CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications by the CEO and CFO pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

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

Dated: June 4, 2009 UROPLASTY, INC.

By /s/ David B. Kaysen

David B. Kaysen
President and Chief Executive Officer

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title / Capacity	Date
/s/ David B. Kaysen David B. Kaysen	President, Chief Executive Officer and Director (Principal Executive Officer)	June 4, 2009
/s/ Mahedi A. Jiwani Mahedi A. Jiwani	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	June 4, 2009
/s/ R. Patrick Maxwell R. Patrick Maxwell	Chairman of the Board of Directors	June 4, 2009
/s/ Thomas E. Jamison Thomas E. Jamison	Director	June 4, 2009
/s/ Lee A. Jones Lee A. Jones	Director	June 4, 2009
/s/ James P. Stauner James P. Stauner	Director	June 4, 2009

/s/ Sven A. Wehrwein

Sven A. Wehrwein