UROPLASTY INC
Form 10KSB
June 29, 2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-KSB
Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934
For the Fiscal Year Ended March 31, 2006

Commission File No. 000-20989
UROPLASTY, INC.
(Name of Small Business Issuer in its Charter)

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

2718 Summer Street NE
Minneapolis, Minnesota 55413-2820
(Address of principal executive offices)
(612) 378-1180
(Issuer s telephone number, including area code)

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

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES þ NOo

Check if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of Company s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES o NOþ

Issuer s revenues for its most recent fiscal year: $6,142,612

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 June 1, 2006 was $9,514,884.

The number of shares outstanding of the issuer s only class of common stock on June 1, 2006 was 6,961,206.

Documents Incorporated By Reference: Portions of the Company s Proxy Statement for its 2006 Annual Meeting of Shareholders (the Proxy Statement), are incorporated by reference in Part III.

Transitional Small Business Disclosure Format: YES o NO þ

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

YES o NOþ

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PART I

Uroplasty, Inc. may from time to time make written or oral **forward-looking statements,** including our statements contained in this report with the Securities and Exchange Commission and in our reports to stockholders, as well as elsewhere. Forward-looking statements are statements such as those contained in projections, plans, objectives, estimates, statements of future economic performance, and assumptions related to any of the foregoing, and may be identified by the use of forward-looking terminology, such as may, expect, anticipate, estimate, goal, continue comparable terminology. By their very nature, forward-looking statements are subject to known and unknown risks and uncertainties relating to our future performance that may cause our actual results, performance or achievements, or industry results, to differ materially from those expressed or implied in any such forward-looking statements. Forward-looking statements are contained in the Management s Discussion and Analysis or Plan of Operation and other sections of this report. Various factors and risks (not all of which are identifiable at this time) could cause our results, performance or achievements to differ materially from that contained in our forward-looking statements. We caution investors that any forward-looking statement contained herein or elsewhere is qualified by and subject to the warnings and cautionary statements contained above and in, particular, in the Risk Factors discussion contained in the Description of Business section of this report.

We do not undertake and assume no obligation to update any forward-looking statement that we may make from time to time.

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. Affecting urinary or fecal control, voiding dysfunctions debilitate millions of adults worldwide and cost billions of healthcare dollars. Since many of these dysfunctions are highly correlated with age, the aging population will demand increasingly better, and less invasive, solutions for these conditions.

We have developed, and are developing, products primarily for the treatment of urinary and fecal incontinence. Our products offer physicians and patients minimally invasive treatment options. All products we currently market are CE marked for European Union clearance (similar to Food and Drug administration (FDA) clearance in the U.S.). Our Macroplastique and other implantable tissue bulking products have not yet been cleared for marketing in the United States.

Macroplastique® Implants, a proprietary, implantable soft tissue bulking product is used for the treatment of both male and female urinary incontinence. When Macroplastique is injected into tissue around the urethra, it stabilizes and bulks tissues close to the urethra, thereby providing the surrounding tissue with increased capability to control the release of urine. Macroplastique is also used to treat vesicoureteral reflux, predominately a pediatric condition in which urine flows backward from the bladder to the kidney. Macroplastique has been sold, since 1991 in over 40 countries outside of the U.S., for urological indications. Our other proprietary, implantable soft tissue bulking agents that we sell outside the United States include PTQ Implants for fecal incontinence, VOX Implants for vocal cord rehabilitation and Bioplastique® Implants for dermal augmentation.

I-Stop Mid-Urethral Sling is a biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. We are the exclusive distributor of this product in the United Kingdom and in the United States. In August 2005 this product received premarket clearance for sale within the United States.

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The Urgent® PC neuromodulation system is a minimally invasive neuromodulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. Using percutaneous tibial nerve stimulation, the product delivers an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. In April 2005, we acquired the exclusive rights to manufacture and distribute this product in the U.S., Canada and all countries recognizing the CE mark. We received regulatory approvals for sale of this product in the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we launched the product for sale in those markets.

Our goal is to develop and commercialize a portfolio of minimally invasive products for the treatment of voiding dysfunctions. We believe that, with a suite of innovative products, we can increasingly garner the attention of key physicians and distributors and enhance market acceptance of our products. The key elements of our strategy are to:

Pursue regulatory approval in the U.S. for our Macroplastique;

Expand our U.S. marketing and sales organization, using a combination of direct and independent reps;

Conduct multi-center, prospective clinical trials for the Urgent PC;

Expand distribution of our products outside of the U.S.; and

Acquire or license complimentary products if appropriate opportunities arise.

We concluded a multi-center human clinical trial using Macroplastique Implants in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency, a weakening of the muscles that control the flow of urine from the bladder. In December 2004, the FDA accepted for filing our pre-market approval submission with respect to Macroplastique for the treatment of adult female stress urinary incontinence. This submission is under review by the FDA and we continue to expect, as we indicated in July 2005, the possible approval by the FDA in late 2007. We will incur substantial expenses in connection with these regulatory activities. Even if we obtain regulatory approval, it may be only for limited uses with specific classes of patients, which may limit the market for our product.

In the United States, we recently staffed our sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. We anticipate further increasing, as needed, our sales and marketing organization in the United States 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 through distributors in other markets.

Voiding Dysfunctions

Voiding dysfunctions affect urinary or fecal control and can result in unwanted leakage (urinary or fecal incontinence) or uncontrolled sensations (overactive bladder symptoms). We believe we are uniquely positioned to offer minimally invasive products to treat each of these voiding dysfunctions.

The Problem of Urinary Incontinence

Urinary incontinence, the uncontrolled leakage of urine, is a problem suffered by millions of people worldwide in varying degrees of severity. Because of the social stigma associated with this condition, it is often underreported. It can result in a substantial decrease in a person s quality of life, and is often the main reason a family moves an elderly person to nursing home care. The Agency for Health Care Policy and Research (AHCPR), a division of the Public Health Service, U.S. Department of Health and Human Services, estimates that urinary incontinence affects about 13 million people in the United States, of which 85% (11 million) are women. The same agency estimates the total cost of treating all types of incontinence (management and curative approaches) in the United States to be $15 billion. Researchers at the University of California, Los Angeles determined a 38% prevalence rate of urinary incontinence among the 23 million adult women surveyed by the National Center for Health Statistics. We expect the incidence of urinary incontinence will rise as the percentage of elderly population grows.

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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. The urinary sphincter and pelvic floor support are also responsible for maintaining continence during periods of physical stress. 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.

For men, urinary incontinence is most often associated with prostate conditions or nerve problems, such as complications arising from diabetes, stroke or Parkinson s disease. Enlargement of the prostate gland (the gland surrounding the male urethra just below the bladder) may impact urinary control. Approximately 400,000 prostate surgeries are performed each year in the United States for prostate enlargement or for prostate cancer. Up to 20% of men undergoing such surgery develop incontinence following the procedure.

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. For the majority of women with SUI (9 million of the 11 million in the U.S.), their incontinence is caused by urethral hypermobility. 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. Stress urinary incontinence can also be caused by intrinsic sphincter deficiency, or the inability of the sphincter muscle to function properly. Intrinsic sphincter deficiency can be due to congenital sphincter weakness or can result from deterioration of the urethral muscular wall due to changes of aging or damage following trauma, spinal cord lesion or radiation therapy. The National Association for Continence (NAFC) estimates up to 15% of female stress urinary incontinence is a result of intrinsic sphincter deficiency. For many women, their SUI is a combination of urethral hypermobility and ISD.

Urge Incontinence - Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate. Urge incontinence often occurs when neurological 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). Clinicians estimate that 30% of women suffering from stress urinary incontinence also exhibit symptoms of urge incontinence. Since prostate enlargement often obstructs the urethra, older men often have urge incontinence coupled with overflow incontinence.

Management and Curative Treatment of Urinary Incontinence

There are two general approaches to dealing with urinary incontinence One approach is to manage symptoms with products such as pads or diapers. The other approach is to undergo curative treatments in an attempt to restore continence, such as injection of urethral tissue bulking agents or by invasive surgeries. We believe the treatment of urinary incontinence should start first with the least invasive therapy and then move to more invasive therapies only when needed.

Management of Urinary Incontinence

Absorbent Products. Absorbent products are the most common form of management for urinary incontinence because men and women can use them without consulting a physician. The cost of adult diapers and pads can be substantial

and create a continuous financial burden for patients. Additionally, this management technique may require frequent changing of diapers and pads to control patient embarrassment due to odor or soiling.

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Behavior Modification. Techniques used in behavior modification include bladder training, scheduled voiding and pelvic floor muscle exercises known as Kegels. Some of the tools used in conjunction with these training regimes are vaginal cones or weights, biofeedback devices and pelvic floor stimulation. Because these techniques rely on active, frequent participation of the individual, these techniques are seldom effective.

Occlusion and Compression Devices. Penile clamps, pessaries and urethral occlusion devices are typically reserved for temporary use. Complications such as tissue erosion, urinary tract infections, edema, pain and obstruction are associated with extended or improper use.

Urinary Catheters and Collection Devices. The type and severity of incontinence and an individual s physical and mental condition determine the choice of catheter. Catheters may be inserted as needed for bladder drainage and may be a closed, indwelling system or an external collection device.

Drug Therapy. Drug treatment is used to manage multiple types of urinary incontinence. Therapeutic drug activity is matched to the individual s urinary dysfunction, e.g., activity targeted to contract muscle tissue of the bladder or bladder neck or to improve the quality of the bladder neck and urethra mucosal lining. Drugs are most often used to treat symptoms of overactive bladder but drugs seldom cure stress urinary incontinence. Common side effects of drugs include dry mouth, constipation and headache. Other potential side effects include urinary retention, nausea, dizziness, blurred vision and the possibility of unwanted interactions with other drugs.

Curative Treatment of Urinary Incontinence

Injectable Uretheral Tissue Bulking Agents. Urethral tissue bulking agents are inserted with a needle into the area around the urethra, augmenting the surrounding tissue for increased capacity to control the release of urine. Hence, these materials are often called bulking agents or injectables. Urethral bulking agents may be either synthetic or biologically derived and are an attractive alternative to surgery because they are considerably less invasive. Active women benefit from the use of urethral bulking agents since they will often return to normal activities in a matter of days instead of weeks of recovery following invasive surgical procedures. Bulking agents also represent a desirable treatment option for the elderly or infirm who may not otherwise be able to withstand the trauma and morbidity resulting from a fully invasive surgical procedure. Additionally, the use of a urethral bulking agent does not preclude the use of more invasive treatments if required.

Biologically derived bulking agents include a patient s own fat cells, polysaccharides (not commercially available in the United States) or bovine collagen. Fat injections involve complex, invasive harvesting of the patient s own fat cells and re-injecting them into the bladder neck. Collagen injections require pre-treatment allergy skin tests and, since the body absorbs collagen over time, the patient may require subsequent re-injections.

Synthetic bulking agents include solid silicone elastomers, pyrolytic carbon-coated beads, and DMSO and polyvinyl alcohol.

Surgery. In women, stress urinary incontinence can be surgically corrected through a procedure in which the physician elevates and stabilizes the urethra and bladder neck, often with a sling to support these structures. Market adoption of sling procedures is demonstrated by over 10% annual growth during the last five years. An estimated 180,000 sling procedures were performed in the U.S. during 2005, with almost half of these procedures using a tension-free sling product, usually implanted in an outpatient setting. Numerous publications cite sling procedure efficacy greater than 85%.

In men, the surgical options for treating urinary incontinence are a male sling or an implanted artificial urinary sphincter, a patient-controlled device that keeps the urethra closed until the patient is ready to urinate. Surgery to place the artificial sphincter requires general or spinal anesthesia.

Uroplasty Solutions for Urinary Incontinence

We believe that we are uniquely positioned with differentiable, minimally invasive products to address both causes of SUI an injectable bulking agent to treat ISD and a tension-free type sling to treat urethral hypermobility.

Macroplastique® Implants

Macroplastique® is an injectable soft-tissue bulking agent used to treat stress urinary incontinence, the most common form of urinary incontinence in women. It is designed to restore the patient s urinary continence immediately following treatment.

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Additionally, men who experience incontinence as a result of prostate surgery are also candidates for Macroplastique treatment.

Macroplastique is a soft-textured, permanent implant placed endoscopically around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone) implants suspended in a biocompatible carrier gel. We believe our compound is better than other commercially available bulking agents because it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site due to its unique composition, shape and size. This reduces the need for follow-up treatments. Additionally, there is no need for special storage, cumbersome preparation or mixing for use or for patient allergy testing.

We currently market Macroplastique outside the U.S. Macroplastique is a outpatient, minimally invasive treatment that offers lower surgical risk with shorter recovery time, and a less expensive alternative when compared to invasive procedures. Its safety and efficacy are evidenced by over 14 years of successful use outside the United States with over 50,000 patients treated. We concluded a multi-center human clinical trial using Macroplastique Implants in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency, a weakening of the muscles that control the flow of urine from the bladder. In December 2004, the FDA accepted for filing our pre-market approval submission with respect to Macroplastique for the treatment of adult female stress urinary incontinence. This submission is under review by the FDA and we continue to expect, as we indicated in July 2005, the possible approval by the FDA in late 2007. We will incur substantial expenses in connection with these regulatory activities. Even if we obtain regulatory approval, it may be only for limited uses with specific classes of patients, which may limit the market for our product.

Although Macroplastique is traditionally implanted with the aid of an endoscope, we also market outside the United States a patented, non-endoscopic product placement kit, or delivery kit, called the Macroplastique Implantation System , or MIS, for office-based treatment of female stress urinary incontinence. Our MIS enables easy and consistent product placement without the use of an endoscope. Following FDA approval of Macroplastique, we intend to seek regulatory approval for the MIS.

I-Stop Sling

We are the exclusive distributor in the United States and the United Kingdom of the I-Stop tape, a biocompatible, tension-free, mid-urethral sling manufactured by CL Medical SAS of Lyon, France. The I-Stop tape has received FDA premarket approval and is CE marked for the treatment of female urinary incontinence due to urethral hypermobility. If the urethra is no longer appropriately supported by the surrounding tissues and ligaments, the urethra may move too easily and may no longer properly close. A sling provides a hammock-type support for the urethra to prevent its downward movement, and associated leakage of urine, during periods of increased abdominal pressure.

I-Stop, the only synthetic, mid-urethral sling made of monofilament knitted polypropylene, has closed loop edges, which we believe make it non-damaging to surrounding tissue without the need for a delivery sheath. We also believe that the I-Stop design provides greater strength and controlled flexibility, and improved resistance to fragmentation, stretching and deformity during the outpatient implant procedure, than competitive sling devices. For patients, we believe that our tape design results in less irritation and fewer overall complications. We believe our product is competitively priced and we offer components to address the retropubic and transobturator surgical approaches.

In May 2005, we entered into a one-year exclusive agreement with CL Medical to distribute the I-Stop in the United Kingdom. The agreement is renewable for up to 2 years, subject to certain performance requirements of us. We are required to purchase a minimum of $266,000 of units in the 12-month period following January 1, 2006, subject to periodic adjustment based on the value of the euro. The purchase price is payable in euros. If we fail to reach our minimum purchase requirement, CL Medical has the right to terminate our exclusive distribution rights in the United Kingdom.

In February 2006 we entered into a six-year exclusive agreement with CL Medical to distribute the I-Stop in the U.S. The agreement is renewable for successive five-year terms, subject to certain performance requirements of us. We are required to purchase a minimum of $363,000 of units in the first 12-month period following January 1, 2006, increasing to approximately $2.6 million of units in the fifth year, for an aggregate commitment of approximately $6.5 million of units over the five-year period, subject to periodic adjustment based on the value of the euro. The

purchase price is payable in euros. If we fail to reach our minimum purchase requirement in any 12-month period, CL Medical has the right to terminate our exclusive distribution rights in the United States. CL Medical has agreed to provide us, without additional charge, with any improvements or modifications it makes to the I-Stop sling and has granted us a right of first refusal for exclusive distribution rights in the United States to any new medical devices or procedures it develops. We have agreed that during,

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and for one year after, the term of this agreement, we will not manufacture our own, or market any other party s tension-free vaginal tape product for the treatment of female stress urinary incontinence. If for some reason CL Medical is prohibited from exporting the I-Stop into the United States, CL Medical is required to supply us with the components necessary to manufacture, package and label the I-Stop for the United States market.

The Problem of Overactive Bladder

Overactive bladder (OAB) is a prevalent and challenging urologic problem affecting 16% of the adult population. An estimated 34 million Americans suffer from overactive bladder, although fewer than 40% seek medical help. A survey of individuals with OAB estimated the total U.S. economic cost of OAB (direct and indirect costs) to be $12 billion. For individuals with overactive bladder, 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. Frequency is a repetitive need to void. Normal urinary voiding is eight times per day. Individuals with an overactive bladder may seek to void over 20 times per day and at least two times during the night, thereby causing significant sleep pattern disturbances. 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 headache.

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

Neuromodulation. Normal urinary control is dependent upon properly functioning neural pathways and coordination among the central and peripheral nervous systems, the nerve pathways, bladder and sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to overactive bladder symptoms. Therapy using neuromodulation incorporates electrical stimulation to target specific neural tissue and jam the pathways transmitting unwanted signals. To alter bladder function, the stimulation must be delivered to the sacral nerve plexus, the neural tissue affecting bladder activity. Neuromodulation for OAB is presently conducted through sacral nerve stimulation or percutaneous tibial nerve stimulation.

The sacral nerve stimulator uses a small device, a neurostimulator, to send mild electrical pulses to the sacral nerve. The sacral nerve is located in the lower back, just above the tailbone. The surgically implanted neurostimulator contains a battery and electronics to create the electrical pulses and is connected to a neurostimulation lead (an insulated wire) containing electrodes through which stimulation is delivered to the nerve. The device is most frequently placed under the skin of the buttock, with the lead under the skin near the spine.

Alternatively, percutaneous tibial nerve stimulation (PTNS) delivers stimulation to the sacral nerve plexus by temporarily applying electrical pulses to the tibial nerve. The tibial nerve is an easily accessed nerve in the lower leg. Neuromodulation using PTNS has a similar therapeutic effect as the implantable sacral nerve stimulator, but requires no surgery. PTNS is minimally invasive, has a low risk of complication and is typically performed in a physician s office.

Uroplasty Solutions for Overactive Bladder

Urgent® PC Neuromodulation System

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix, Inc., an Andover, Minnesota medical device company, the exclusive rights to manufacture and market the Urgent® PC Neuromodulation System for the U.S., Canada and all countries recognizing the CE mark. The Urgent PC is a minimally invasive nerve stimulation device designed for office-based treatment of urge incontinence, urinary urgency and urinary frequency

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symptoms of an overactive bladder. Using percutaneous tibial nerve stimulation near the ankle, the product 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 non-surgical neuromodulation device in the U.S. market for treatment of overactive bladder symptoms. Components of the Urgent PC system include a hair-width needle electrode, a lead set and an external, handheld, battery-powered stimulator. For each 30-minute office-based therapeutic session, the physician temporarily inserts the needle electrode in the patient s lower leg and connects the electrode to the stimulator. Typically, a patient undergoes 12 treatment sessions at one-week intervals, with follow up treatments as required to maintain symptom reduction.

Under our agreement with CystoMedix, we are responsible for regulatory applications and compliance within all markets outlined in the agreement. Although the Urgent PC as marketed by CystoMedix was CE marked and 510(k) cleared, following minor revisions to the product, we secured 510(k) clearance for the device in October 2005 and CE mark in November 2005. Subsequently we launched the product for sale. We have since then developed a second generation Urgent PC, and in June 2006, received for it the 510(k) clearance, CE Mark and regulatory approval to sell in Canada.

In connection with the agreement with CystoMedix, we purchased 75% of CystoMedix s inventory of component parts and subassemblies for $25,000. We paid an initial royalty payment of $225,000 in May 2005 and paid an additional aggregate of $250,000 in royalties in monthly installments through May 2006. During the agreement s term, we will pay CystoMedix further royalties of 7% of our net product revenues from the sale of licensed products, offset by payments made against the above $250,000 royalty amount. We agreed to sell licensed products we manufacture back to CystoMedix, on a non-exclusive basis, on terms and for such price as we may mutually negotiate for CystoMedix s own sales outside of the territories exclusively licensed to us.

Our five-year agreement with CystoMedix provides no renewal provision. Between January 2006 and June 2008, we may elect to purchase all of CystoMedix s assets. The option price is $3,485,000, reduced by up to $50,000 of liabilities assumed by us. After April 2007 the option price will increase at a rate of 10% per year. The option price is payable in shares of our common stock valued at the average of the closing bid price of our shares for the 20 trading days prior to our exercise of the option. If we exercise our option, we also assume up to $1.4 million of bridge loan advances made to CystoMedix by its Chairman. We would repay up to $1.1 million of the bridge loan advances at closing and would issue our common stock for the balance of the bridge loan based on the above option price. We also have certain rights of first refusal to acquire CystoMedix s assets in the event CystoMedix receives a third party offer in advance of any exercise of our option.

The Problem of Fecal Incontinence

Fecal incontinence, prevalent in 2-6% of the adult population, with women suffering up to four times more often than men, is an extremely disabling and embarrassing condition. Approximately 25% of women with stress urinary incontinence are also diagnosed with fecal incontinence.

Fecal continence relies on an intact and functioning anal sphincter. The internal anal sphincter (IAS) provides most of the resting anal pressure and is the main muscle responsible for the prevention of anal leakage. Degeneration or disruption of the IAS characteristically leads to fecal incontinence or soiling. Degeneration can result from childbirth, surgical trauma or accident.

Treatment of Fecal Incontinence

The internal sphincter cannot be surgically repaired, as it is extremely thin (approximately 2-3 mm) and, as a circular muscle, is under tension. Antidiarrheal drugs and diet modification help some patients, but this is not a satisfactory, long-term solution for most patients.

Uroplasty Solutions for Fecal Incontinence

We have, and are developing additional, minimally invasive products to address fecal incontinence. Our PTQ Implants offer a minimally invasive treatment for patients with fecal incontinence. They are soft-textured, permanent implants. For treatment of fecal incontinence, PTQ Implants are implanted circumferentially into the submucosa of the anal canal. Injection creates a bulking and supportive effect similar to that of Macroplastique injection for the treatment of stress urinary incontinence. The product is CE marked and currently sold outside the U.S. in various international markets. We also secured CE mark for the application of percutaneous tibial nerve stimulation for the

treatment of fecal incontinence. Our Urgent PC is sold for the treatment of fecal incontinence in countries recognizing the CE mark.

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Other Uroplasty Products

In addition to urological applications, we market our proprietary tissue bulking material outside the United States for reconstructive and cosmetic plastic surgery under the trade name Bioplastique® Implants and for otolaryngology vocal cord rehabilitation applications under the trade name VOX® Implants.

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

Marketing, Distribution and Sales

We currently sell two products in the United States the I-Stop Sling and the Urgent PC Neuromodulation System. We received regulatory approvals for sale of our Urgent® PC Neuromodulation System, the only minimally invasive nerve stimulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency, in the United States and Canada in October 2005 and in Europe in November 2005. Subsequently, we launched this product for sale in those markets.

Our U.S. sales organization consists of a direct field-based sales management group and a nationwide network of independent sales representatives. We anticipate continuing to increase our sales and marketing organization, as needed, to support the sales growth.

Outside of the United States, in addition to our UrgentÒ PC Neuromodulation system, we market and sell Macroplastique and related ancillary products, PTQ Implants, VOX Implants and Bioplastique Implants, and, in the United Kingdom we also sell the I-Stop sling. We sell our products primarily through a direct sales organization in the United Kingdom. In all other markets we sell our products primarily through distributors. International sales managers in The Netherlands manage and train a network of distributors in approximately 40 countries, including Canada, Australia, countries within Europe and Latin America. Each of our distributors has a territory-specific distribution agreement, including requirements indicating they may not sell injectable products that compete directly with Macroplastique. Collectively, our distributors accounted for approximately 65% and 70% of total net sales for fiscal 2006 and 2005, respectively.

We use clinical studies and scientific community awareness programs to demonstrate the safety and efficacy of our products. This data is important to obtain regulatory approval and to support our sales staff and distributors in securing product reimbursement in their territories. Publications of clinical data in peer-reviewed journals add to the scientific community awareness of our products, including therapeutic applications, treatment techniques and expected outcomes. Our clinical research department provides a range of activities designed to support surgeons in their clinical evaluation study design, abstract preparation, manuscript creation and/or review and submission. This team works closely with our sales and marketing and regulatory departments in the area of technical support, submissions, literature review, and analysis and synopsis of technical presentations and publications.

Researchers have designed clinical trials to provide outcome evidence on products developed by us. These include randomized controlled trials on our PTQ Implants, Macroplastique Sling Support Kit (MIS-SK) and a multi-center prospective study on the efficacy of the Urgent PC. Evidence-based clinical research broadens the surgeons acceptance by providing detailed information related to product safety and efficacy when applied to patient selection and comparative surgical and non-surgical treatment regimens. Only by recognition of the complexity of our product, indications, analysis of the contributing variables and presentation and publication of the clinical outcomes, will we provide the physicians, patients and reimbursement systems with the evidence they require to make informed decisions.

Manufacturing and Suppliers

We manufacture our tissue bulking products at our own facilities. We manufacture components in the United States and finished products in The Netherlands. Our facilities utilize dedicated heating, ventilation and high efficiency particulate air (HEPA) filtration systems to provide a controlled working environment. Trained technicians perform all critical manufacturing processes in a cleanroom environment according to validated written procedures. An outside vendor sterilizes our products using validated methods and returns the products to us for final inspection and testing.

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Our manufacturing facilities and systems are periodically audited to ensure compliance with ISO 13485 (medical device quality management systems), and applicable European and Canadian medical device requirements. Our facilities and systems were last audited by AMTAC Certification Services in January 2005. No major deficiencies were noted, and we were found to be in compliance with all standards and requirements audited.

Our facilities also need to be compliant with U.S. federal Quality System Regulations (QSR). While we believe we are compliant with QSR, our facilities have not yet been audited by the FDA for such compliance, and there can be no guarantee that we will pass the FDA compliance audit. We are also subject to additional state, local, and U.S. federal government regulations applicable to the manufacture of our products.

CL Medical designs and manufactures the I-Stop sling. Pursuant to our distribution agreements with CL Medical, we are the exclusive distributor of the I-Stop sling in the United States and the United Kingdom. Among other things, we are required to purchase a minimum number of I-Stop product sets from CL Medical.

Under our manufacturing and distribution agreement with CystoMedix, Inc., we are responsible for the manufacture of the Urgent PC device. We currently subcontract the manufacture of major subassemblies for the product.

We purchase medical grade materials for use in our finished products from several single source suppliers. Our quality department has qualified these suppliers. Although we believe our supply sources could be replaced if necessary without due disruption, it is possible that the process of qualifying suppliers for certain raw materials 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 commercialized tissue bulking agents, urethral sling products and neurostimulation devices. Indirect and future competitors include drug companies and 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 and cost, availability of third-party reimbursement, marketing and sales coverage and the existence of meaningful patent protection. In addition to addressing the decision factors, our ability to effectively 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.

Soft-tissue injectable bulking agents competing directly with Macroplastique®, both outside and in the U.S. include Contigen® and Tegress®, both FDA-approved bulking agents manufactured by C.R. Bard, Inc.; Zuidex® and Deflux® (Deflex FDA approved for VUR use only) manufactured by Q-Med AB; Durasphere® (FDA-approved for female SUI) manufactured by Carbon Medical Technologies; and Coaptite® manufactured by BioForm, Inc. for Boston Scientific. In contrast to the competitors products currently approved for sale, Macroplastique, marketed outside the United States since 1991, 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 test prior to the procedure. The silicone-elastomer material has been studied for over 50 years in medical use for such urological applications as artificial urinary sphincters, penile implants, stents and catheters. Our patented Macroplastique® Implantation System offers a unique, non-endoscopic, minimally invasive out-patient procedure that can be performed in the physician s office.

Sling procedures have become the preferred method for treating urethral hypermobility. The tension-free sling market is dominated by Gynecare s TVT Tension-free Support device. Other companies competing in this market include American Medical Systems, C.R. Bard, Boston Scientific and Mentor Corporation. We believe our I-Stop sling offers benefits of multiple surgical approaches for the physician and a design to resist stretching, deformity and fragmentation.

The Urgent®PC neurostimulation device is an alternative to the more invasive Medtronic InterStim® device. The Medtronic unit, which stimulates the sacral nerve, requires surgical implantation in the upper buttocks or abdomen. In contrast, the Urgent PC device 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 neuromodulation. 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 U.S.

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Many medications treat symptoms of overactive bladder, some by preventing unwanted bladder contractions, others by tightening the bladder or urethra muscles and some 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) and Flomax® (Abbott Laboratories).

Many of our competitors and potential competitors have significantly greater financial, manufacturing, marketing and distribution resources and experience than we have. 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 design, 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 U.S. Food and Drug Administration, or FDA, the European Union and other analogous agencies.

United States

Our products are regulated in the Unites States as medical devices by the FDA under the Food, Drug and Cosmetic 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, may submit a pre-market notification (510(k) clearance) requesting permission for commercial distribution.. Devices deemed by the 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 (PMA) application. The 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.

510(k) Clearance. To obtain 510(k) clearance, the pre-market notification must demonstrate that the proposed device is substantially equivalent in intended use and in safety and effectiveness to a previously 510(k) cleared device or a device that was commercially distributed before May 28, 1976 and for which FDA has not yet called for submission of a pre-market approval application. The FDA attempts to respond to a 510(k) pre-market notification within 90 days of submission of the notification, but the response may be a request for additional information, sometimes including clinical data. As a practical matter, 510(k) clearance can take significantly longer than 90 days, including up to one year or more.

After a device receives 510(k) clearance for a specific intended use, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that would constitute a major change to the intended use of the device will require a new 510(k) pre-market notification submission or, depending upon the changes, could require pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA

can review any such decision. If the FDA disagrees with a manufacturer s determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) clearance

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or pre-market approval is obtained. Also, in these circumstances, a company may be subject to significant regulatory fines or penalties.

Pre-market Approval. A pre-market approval application must be submitted if the device cannot be cleared through the 510(k) process. The pre-market approval process is much more demanding than the 510(k) notification process. A pre-market approval applicant must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the pre-market approval process, applicants must file an Investigational Device Exemption, or IDE, application prior to commencing human clinical trials. If the IDE application is approved by the FDA, human clinical trials may begin at a specific number of investigational sites with a maximum number of patients. The results of clinical testing may not be sufficient to obtain approval of the product.

After the FDA determines that a pre-market approval application is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted pre-market approval application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during this review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulations. New pre-market approval applications or supplemental pre-market approval applications are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the pre-market approval process. Pre-market approval supplements often require submission of the same type of information as a pre-market approval, except that the supplement is limited to information needed to support any device changes not covered by the original pre-market approval application, and may not require as extensive clinical data as the original submission or the convening of an advisory panel.

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

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

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

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

post-market surveillance activities monitor use of the products placed in the market place; and

notices of correction or removal, and recall regulations.

FDA Approval Status of Our Products. The FDA has determined that urethral tissue bulking agents, such as Macroplastique, are Class III devices and require FDA clearance of a pre-market approval application. In 1999, the FDA approved our IDE application for the use of Macroplastique in a clinical study for the treatment of stress urinary incontinence. In 2000, we commenced human clinical trials at multiple sites. We concluded the 12-month patient follow up visits for this study and, in 2004 submitted a pre-market approval application. This submission is under review by the FDA and we continue to expect, as we indicated in July 2005, the possible approval by the FDA in late 2007. Even if we obtain regulatory approval, it may be only for limited uses with specific classes of patients, which may limit the market for our product.

In August 2005, the I-Stop product received premarket clearance for sale within the United States.

The Urgent PC device previously received 510(k) clearance for U.S. marketing by the FDA. However, following product revisions, we submitted our 510(k) pre-market application in August 2005. We received 510(k) clearance in October 2005 for our version of the Urgent PC device. Following development of our second generation of the Urgent PC, in May 2006 we submitted a special 510(k) pre-market application. With regards to our second generation Urgent PC, in June 2006, we received the CE mark and approval from Therapeutic Products Directorate of Health to sell in Canada.

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FDA Oversight of Manufacturing Operations. The Food, Drug and Cosmetics Act requires that medical devices be designed and manufactured in accordance with the 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 the FDA to inspect our manufacturing facilities on a periodic basis to monitor our compliance with Quality System Regulations.

Although our manufacturing facilities and processes have been inspected and certified in compliance with ISO 13485, applicable European medical device directives, and Canadian Medical Device Requirements, they have not been inspected by the FDA for compliance with Quality System Regulations. We will be required to have a FDA inspection prior to the pre-market approval of our Macroplastique product for sale in the U.S. We cannot assure you that our facilities and processes will be found to comply with Quality System Regulations and there is a risk that approval will, therefore, be delayed by the FDA until such compliance is achieved.

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 assurance 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.

We received CE marking approval for Macroplastique in 1996 for the treatment of male and female stress urinary incontinence and vesicoureteral reflux; for the Urgent PC for the treatment of fecal incontinence, and overactive bladder symptoms of urinary urgency, urinary frequency and urge incontinence. In addition, we received CE marking for PTQ Implants in 2002 for the treatment of fecal incontinence; for VOX Implants in 2000 for vocal cord rehabilitation applications; and for Bioplastique Implants in 1996 for dermal augmentation applications. The I-Stop sling received CE marking approval in July 2002. Our European 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 the 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 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.

Third-Party Reimbursement

In both U.S. markets and markets outside the U.S., sales of our products will depend in part on the availability of reimbursement from third-party payors. 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 and other tissue bulking products 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.

In the U.S., 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;

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

payment amount.

Reimbursment for tension-free sling products has been previously addressed by numerous competitors. As a result coding, coverage and payment for the I-Stop Mid-Urethral Sling is already well-established.

As a relatively new therapy, nerve simulation using the Urgent PC has not been assigned a reimbursement code unique to the technology. However, a number of practitioners are using an existing reimbursement code that closely describes the procedure. In addition, Aetna and Blue Cross Blue Shield of Minnesota and Maryland have published policies providing coverage for PTNS under an existing reimbursement code. We will need to continue to work with third-party payers for coverage policies and the American Medical Association to develop definitive and uniform reimbursement for the theraphy. In addition, we will need to provide customer reimbursement support as we market the product and secure medical community acceptance.

We believe, but cannot confirm, that there are appropriate codes available to describe endoscopic use of Macroplastique to treat female SUI. We expect that, upon FDA approval to market Macroplastique, we will need to foster coverage policies and payer acceptance to support the U.S. launch. There is no guarantee that Macroplastique will be reimbursed at the levels expected by us, if at all.

Patents, Trademarks and Licenses

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

We hold multiple patents covering our Macroplastique materials, processes and applications. As of the date of this report, we have four issued U.S. patents and 19 granted patents in the United Kingdom, Japan, Germany, France, Spain, Italy, Portugal, The Netherlands and Canada. Our patents will expire in the U.S. 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 U.S. 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. CystoMedix and CL Medical also have certain patent rights which they licensed to us as part of their respective manufacturing and distribution agreements. We are awaiting prosecution of the patent protection applications we filed in 2006 for the Urgent PC.

In 1992, we agreed to settle alleged patent infringement claims by Collagen Corporation (now Inamed Corporation). Under the settlement agreement, we pay Collagen a royalty of 5% of net sales in the U.S. of Macroplastique products with a minimum, through May 1, 2006, of $50,000 per year.

Although we intend to apply for additional patents and vigorously defend issued patents, management believes our business success will depend primarily upon our development and sales and marketing skills, and the quality and economic value of our products rather than on our ability to obtain and defend patents.

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 have registered Macroplastique®, Uroplasty® and Bioplastique® as trademarks with the U.S. Patent and Trademark Office. Our non-registered trademarks include VOX and PTQ , for which trademark registration applications are pending in the U.S. Patent and Trademark Office and in European countries. In addition, Macroplastique is registered in numerous European countries. CystoMedix has U.S. registration of the Urgent®PC trademark and has licensed the mark to

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us as part of our exclusive manufacturing and distribution agreement. In addition, CL Medical has licensed its non-registered trademark for the I-Stop sling to us as part of our agreement with it.

We have a royalty agreement with three individuals, two of whom are former officers and directors. Under this royalty agreement, we pay aggregate royalties of three to five percent of net sales of Macroplastique and Bioplastique, 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.

In October 1998, we received an absolute assignment from a British surgeon of a patent relating to the Macroplastique Implantation System in return for a royalty of £10 for each unit sold during the life of the patent. We began commercialization of the product outside the U.S. in March 2000.

Research and Development

We have a research and development program to develop new incontinence products. We are also continually evaluating product potential improvements, and new methods and devices for the implantation of and new applications for Macroplastique. Research and development expenses also include the costs of clinical studies and regulatory compliance. Our expenditures for research and development totaled $3.3 and $2.3 million for fiscal 2006 and 2005, respectively. None of these costs were borne directly by customers.

Product Liability

The medical device industry is subject to substantial litigation. As a manufacturer of a long-term implantable device, we face an inherent risk of liability for claims alleging adverse effects to the patient. We currently carry $2 million of worldwide product liability insurance, plus another policy specific to the United Kingdom only. There can be no assurance, however, our existing insurance coverage limits are adequate to protect us from any liabilities we might incur. There can be no assurance that liability claims will not exceed coverage limits. 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 2006 and 2005 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During fiscal 2006, two customers accounted for approximately 14% and 11% of our net sales. During fiscal 2005, the same two customers accounted for approximately 15% and 11% of our net sales.

Employees

As of March 31, 2006, we had 55 employees, of which 51 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, is the manufacturer of Macroplastique, Bioplastique, VOX Implants, PTQ Implants and of all their accessories,. Products are sold primarily through distributors.

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Uroplasty LTD	Incorporated in the United Kingdom and acts as the sole distributor of Urgent PC, Macroplastique, Bioplastique, PTQ Implants, all of their accessories, and wound care products in the United Kingdom and Ireland. Also distributes the I-Stop in the United Kingdom. Products are sold primarily through a direct sales organization.
Bioplasty BV	Incorporated in The Netherlands and is the distributor of Bioplastique to subdistributors, and distributes wound care products in The Netherlands. We plan to merge this subsidiary with Uroplasty BV in fiscal 2007.

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-KSB 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, 2006, we had an accumulated deficit of approximately $11 million primarily as a result of costs relating to the development, including seeking regulatory approvals, and commercialization of our Macroplastique, I-Stop® tape, Urgent® PC neuromodulation system and related products. We expect our operating expenses relating to sales and marketing activities and product development, including seeking United States regulatory approval for Macroplastique, will continue to increase during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability to obtain FDA approval to market Macroplastique, and our ability to achieve widespread market acceptance for our products, which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

If we fail to receive or experience a significant delay in receiving regulatory approvals for sale of our products, our ability to generate revenues will be limited and our business prospects may suffer.

We cannot sell Macroplastique in the United States until we obtain the requisite FDA approvals. If we suffer delays in obtaining or fail to receive regulatory approvals, our ability to generate revenues from the sale of these products will be limited and our future growth may be significantly hampered.

In the U.S., we have submitted a pre-market approval application with respect to Macroplastique. The pre-market approval process is very expensive, uncertain and time-consuming and could materially delay our product coming to market. This submission is under review by the FDA and we continue to expect, as we indicated in July 2005, the possible approval by the FDA in late 2007. We will incur substantial expenses in connection with these regulatory activities. Even if we obtain regulatory approval, it may be only for limited uses with specific classes of patients, which may limit the market for our product.

We are primarily dependent on sales of one product and our business would suffer if sales of this product decline.

We are dependent on sales of our products that contain our Macroplastique bulking agent. Our Macroplastique product line accounted for 67% and 76%, respectively, of total net sales during fiscal 2006 and 2005. If our Macroplastique products were no longer available for sale in any key market because of regulatory, intellectual property or any other reason, our net sales from these products would significantly decline. A significant decline in our net sales could also negatively impact our product development activities and therefore our business prospects.

We are unable to predict how quickly or how broadly our products will be accepted by the market. 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.

Although some our products received FDA approval, market acceptance is uncertain. Our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefits and cost-effectiveness of our products

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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. 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.

Our products and facilities are subject to extensive regulation with which compliance is costly and which exposes us to penalties for non-compliance. We may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all, which could adversely affect our business and results of operations.

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, labeling and record keeping procedures. We are required to obtain FDA 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 for sale. Any failure to obtain 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.

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.

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

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

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party s intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management; or
- result in our customers or potential customers deferring or limiting their purchases or use of the affected products until resolution of the litigation.

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

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

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 $2 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

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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.

If we are not able to successfully scale-up production of our products, our sales and revenues will suffer.

In order to commercialize our products in the United States and international markets, we need to be able to produce, or subcontract the production, of our products in a cost-effective way on a large scale to meet demand, while maintaining high standards for quality and reliability. If we fail to successfully commercialize our products, we will not be profitable.

We may experience manufacturing and control problems as we begin to scale-up our future manufacturing operations, and we may not be able to scale-up manufacturing in a timely manner or at a reasonable cost to enable production in sufficient quantities. If we experience any of these problems, we may not be able to have our products manufactured and delivered in a timely manner.

The I-Stop sling is designed and manufactured by CL Medical in France for our distribution in the United States and the United Kingdom. If CL Medical experiences problems with manufacturing or control, encounters regulatory or compliance problems, or incurs delays, we may not receive the I-Stop product in a timely manner. This would limit our ability to generate revenues.

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. 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, approval of our products by the European Union, the FDA or other relevant authorities could be delayed or denied and our sales and revenues will suffer.

Approval of our products could be delayed by the FDA, European Union or other related authorities if our manufacturing facilities do not comply with applicable manufacturing requirements. The FDA s Quality System Regulations impose elaborate testing, control, document and other quality assurance procedures. Canada and the European Union also impose requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by us or CL Medical to comply with these requirements could prevent us from obtaining FDA approval for our products and from marketing our products in the United States. We cannot assure you that our manufacturing facilities will comply with applicable requirements on a timely basis or at all.

Even with approval to market our products in the European Union, the United States and other countries, we must continue to comply with relevant manufacturing 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 increase our sales force and expand our distribution channels, our sales and revenues will suffer.

To date, we have sold our products in foreign markets through a network of independent distributors and our direct sales force. 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 and to recruit additional sales personnel. We may not be able to attract distributors who are willing to commit the necessary resources to market and sell our products to the level of our

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expectations. In the United States, we have a sales organization consisting of a direct sales management group 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 will need to raise additional debt or equity financing to expand our sales and marketing organizations. We have incurred and likely will incur some additional related expenses in advance of any anticipated regulatory approval, which we could not recoup if we do not receive such approval. We also may not be able to hire, train and motivate qualified sales and marketing personnel. Failure to expand our distribution and sales channels will adversely affect our sales and revenues.

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. In fact, we have an option to acquire the assets of CystoMedix, Inc., the company that has licensed the Urgent® PC technology to us.

Any product candidate we license or acquire may require additional development efforts prior to sale, including clinical testing and approval by the FDA. Product candidates may fail to receive or experience a significant delay in receiving FDA approval. 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 (including that of CystoMedix, of which there is no assurance), our business, financial condition and the results of operations could be negatively affected because:

- we may be unable to integrate the acquired business 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.

The loss of our key customers could result in a material loss of revenues.

During fiscal 2006, we had two customers that accounted for approximately 14% and 11% of our net sales. During fiscal 2005, the same two customers accounted for approximately 15% and 11% of our net sales. As a result, we face the risk that one or more of our key customers may decrease its or their business with us or terminate its or their relationships with us. Any decrease in business from these customers, if we are unable to replace them, could result in a material decrease in our revenue. This could adversely affect our financial condition.

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 breast implant industry became the subject of significant controversies surrounding the possible effects upon the human body of the use of 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 by us and others of solid silicone in medical devices implanted in the human body will not result in negative publicity.

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 substantially all of our net sales from 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

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States customers of the already FDA-approved products and we obtain requisite FDA approvals for the remaining 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, most 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.

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

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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.

If we are unable to continue to develop and market new products and technologies, we may experience a decrease in demand for our products or our products could become obsolete, and our business would suffer.

We are continually engaged in product development and improvement programs, and we expect new products to represent a significant component of our future business. We may not be able to compete effectively with our competitors unless we can keep up with existing or new products and technologies in the urinary and fecal incontinence market. If we do not continue to introduce new products and technologies, or if those products and technologies are not accepted, we may not be successful and our business would suffer. Moreover, our clinical trials have durations of several years and it is possible that competing therapies, such as drug therapies, may be introduced while our products are still undergoing clinical trials. This could reduce the potential demand for our products and negatively impact our business prospects. Additionally, our competitors new products and technologies may beat our products to market, may be more effective or less expensive than our products or render our products obsolete.

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. We may not have adequate resources to market our products successfully against larger competitors which have more resources than we do. If we cannot market our products successfully, our business and results of operations would be adversely affected.

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 urinary and fecal 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 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 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. We believe that the ease of obtaining, and the amount of, reimbursement for urinary incontinence treatment has a significant impact on the decisions of health care providers regarding treatment methods and products. Accordingly, changes in the extent of coverage or a reduction in reimbursement rates under any 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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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.

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 our information systems fail or if we experience an interruption in their operation, our business and results of operations could be adversely affected.

The efficient operation of our business is dependent on our management information systems. We rely on our management information systems to effectively manage accounting and financial functions, order entry, order fulfillment and inventory replenishment processes, and to maintain our research and development and clinical data. The failure of our management information systems to perform as we anticipate could disrupt our business and product development and could result in decreased sales, increased overhead costs, excess inventory and product shortages, causing our business and results of operations to suffer. In addition, our management information systems are vulnerable to damage or interruption from:

earthquake, fire, flood and other natural disasters;

terrorist attacks and attacks by computer viruses or hackers; and

power loss or computer systems, Internet, telecommunications or data network failure.

Any such interruption could adversely affect our business and results of operations.

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

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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.

We will 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 associated with obtaining FDA approval of Macroplastique;
- the timing and cost involved in manufacturing scale-up and in expanding our sales, marketing and distribution capabilities in the U.S. market;
- 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 and regulatory developments; and
- the cost involved in protecting our proprietary rights.

We will need to raise additional debt or equity financing to continue funding for product development and continued expansion of our sales and marketing activities, and ultimately, we will need to achieve profitability and generate positive cash flows from operations to fund our operations and grow our business. As such we plan to raise additional equity capital in fiscal 2007, but there can be no guarantee that we will be successful. We currently have no committed sources of, or other arrangements with respect to, additional financing except for the recently established credit lines for $1.3 million and a term loan of $100,000 as described in Note 9, Subsequent Events, to the financial statements. We cannot assure you that we will be able to obtain additional financing on acceptable terms or at all. Our failure to obtain financing when needed could have a material adverse effect on us. 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.

You may be unable to sell your investment.

There is only a limited trading market for our common stock, which is quoted on the AMEX. 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. Further, our common stock is subject to the penny stock rules under The Securities and Exchange Act of 1934. The penny stock rules require brokers who sell penny stocks to persons other than established customers and institutional accredited investors to complete required documentation, make suitability inquiries and provide investors with information concerning the risks of trading in the security. The additional burdens imposed on brokers by these requirements could discourage brokers from effecting transactions in our common stock. Consequently, an investor is likely to find it more difficult to sell our common stock.

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 FDA approval of Macroplastique;
- market acceptance of our products;
- the success of our efforts to acquire or license additional products;

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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.

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 filed a registration statement under the Securities Act covering the issuance of up to 806,218 shares of common stock that certain existing security holders may acquire upon the exercise of outstanding warrants. The registration statement has not yet been declared effective therefore these shares are currently not freely tradeable. As of May 31, 2006, we have outstanding 1,180,928 shares of registered common stock issuable upon exercise of warrants granted to the security holders in connection with our April 2005 private placement.

As of May 31, 2006, we had 949,327 shares of common stock subject to outstanding options granted under our former 1995, 1997 and 2002 Stock Option Plans. These shares are registered for public resale by the holders of those options. As of May 31, 2006 we had 38,000 shares of common stock subject to outstanding options granted under our 2006 Stock and Incentive Plan. In addition, as of May 31, 2006 we had 1,240,000 shares of common stock subject to outstanding options granted from various stock option plans. Further, if we exercise our option to acquire the assets of CystoMedix, we will need to issue our common stock to CystoMedix for the purchase price. As of May 31, 2006, 1,832,643 outstanding options are immediately exercisable.

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 the requirements relating to internal controls and all other aspects of Section 404 by our March 31, 2008 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 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.

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Changes in accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and would also negatively impact our results of operations.

The Financial Accounting Standards Board has issued Statement No. 123(R), *Share-Based Payments*, SFAS 123(R), which requires all companies to treat the fair value of stock options granted to employees as an expense, beginning in the first fiscal year that begins after December 15, 2005, for small business issuers. Accordingly, SFAS 123(R) is effective for us beginning in fiscal 2007. For fiscal 2006 and prior years, we generally have not recorded compensation expense in connection with stock option grants to employees. Because in the future we will expense the fair value of employee stock option grants, granting stock options is less attractive because of the additional expense recognized associated with these grants, which will negatively impact our results of operations. If we had adopted the fair value method for fiscal 2006 and 2005, our net loss for the respective fiscal years would have been $3,062,324, and $2,321,745 higher than reported and net loss per share would have increased by $0.46, and $0.50 per common share, respectively. Nevertheless, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program.

In February 2006, our Board of Directors approved a plan to accelerate, effective February 2, 2006, the vesting of out-of-the-money, unvested stock options previously granted to our employees, officers and directors. An option was considered out-of-the-money if the stated exercise price exceeded $2.85, the then closing price of our common stock. Pursuant to this action, options to purchase approximately 0.4 million shares of our common stock with a weighted average exercise price of $4.49 per share became exercisable immediately.

We accelerated the vesting of these options to minimize the amount of compensation expense we must recognize upon adoption of SFAS No. 123(R). None of these options had intrinsic value at the acceleration date under APB 25. We expect that the acceleration of the vesting of these options reduced the pre-tax stock option expense by approximately $1.4 million, in the aggregate, calculated using the Black-Scholes option valuation model, that we would have otherwise recognized over the next three fiscal years, upon adoption of SFAS No. 123(R). We have included the charge attributed to the accelerated vesting of the options in the pro forma disclosures to our consolidated financial statements for the fiscal year ended March 31, 2006. However, certain outstanding options, with a cashless exercise provision, and certain outstanding options classified as liabilities, could result in a significant charge to compensation expense in future periods, as we will mark those options to fair value at each reporting period until settlement. Also, additional options as granted to attract or retain new employees could result in significant charge to compensation expense.

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 authorize our board of directors to issue up to 20 million shares of stock which, without stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights. With these rights, the holders of such shares could make it more difficult for a third party to acquire us. In addition, our articles of incorporation provides 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.

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ITEM 2. DESCRIPTION OF PROPERTY

We currently lease on a month-to-month basis a 13,705 square-foot (reduced to 6,205 square feet in July 2006) office, warehouse, laboratory and production facility for our corporate headquarter in Minneapolis, Minnesota. Effective May 2006 we entered into an eight-year lease for an 18,259 square foot facility in Minnetonka, Minnesota for our new corporate headquarter. We expect to fully relocate to our new corporate headquarter in the third calendar quarter of 2006. We own 9,774 square feet of office and warehouse space in Geleen, The Netherlands and lease 2,330 square feet of office, warehouse, laboratory and manufacturing space through June 2007 in Eindhoven, The Netherlands. In addition, we lease 5,230 square feet of office and warehouse space through September 2011 (subject to our right to terminate the lease in September 2006) in Reading, United Kingdom. We intend to terminate this lease in September 2006 and consolidate our operations 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 COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information. As of the date hereof, there is only a limited public trading market for our Common Stock. In October 2005, we listed our common stock on the American stock Exchange under the symbol UPI. Previously, our common stock was quoted on the OTC Bulletin Board under the symbol UPST.OB.

The following table sets forth the high and low closing prices for our common stock for our fiscal year ended March 31, 2006, as reported on the American Stock Exchange and the high and low bid prices for our common stock as reported by the OTC Bulletin Board, as applicable, for the periods indicated. The OTC quotations represent interdealer prices, without retail markup, mark down or commission, and do not necessarily represent actual transactions.

Fiscal Quarters	Low	High
First Quarter	$ 3.91	$ 4.90
Second Quarter	2.60	5.80
Third Quarter	2.60	3.80
Fourth Quarter	2.30	3.14

As of March 31, 2006, approximately 523 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, 2006.

	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)**
Equity Compensation Plans Approved by Security Holders	624,993	$ 3.25	39,100(2)
Equity Compensation Plans Not Approved by Security Holders (1)	1,363,334	$ 4.07	10,431
Total	1,988,327	$ 3.81	49,531

(1) The following is a brief description of the various equity compensation plans not

approved by our stockholders.

Our 1995 Stock Option Plan provides for the grant only of non-qualified stock options to our employees, directors, non-employees and consultants. At March 31, 2006, 340,000 unexercised options were outstanding, and we have not granted additional options subsequently under this plan. This plan was terminated on May 3, 2006 and no new option grants may be awarded from this plan.

We have also granted options from outside of our 1995 Stock Option Plan. In January 2005, we granted options to acquire 400,000 and 100,000 shares of our common stock at an exercise price of $5.19 per share, respectively, to Sam B. Humphries, our former President and Chief

Executive Officer, pursuant to an employment agreement, and Daniel G. Holman, our former Chairman, for his service as a member of the Board, pursuant to an employment and consulting agreement. The options for both executives are fully vested and have a term of 10 years. In April 2003, we entered into a consulting agreement with Executive Advisory Group (EAG) for general business advisory services and assistance. Mr. Humphries is President of EAG. We granted EAG a five-year option to purchase up to 50,000 shares of our Common Stock, exercisable at $2.80 per share. In April 2003, we entered into a consulting agreement with C.C.R.I. Corporation for investor relations services and issued five-year

warrants to purchase 100,000 of our shares. Half of these warrants are exercisable at $3.00 per share and the other half are exercisable at $5.00 per share. In November 2005, we granted options to acquire 100,000 shares of our common stock at an exercise price of $3.00 per share to Mahedi A. Jiwani, our Chief Financial Officer, pursuant to an employment agreement. These options are fully vested and have a term of 10 years. In May 2006, we granted options to acquire 300,000 shares of our common stock (of which 100,000 are vested as of May 31, 2006) at an exercise price of $2.50 per share to David B. Kaysen, our President and Chief Executive Officer, pursuant to an employment agreement. These options have a term of 10 years.

In addition, we have outstanding an aggregate of 850,000 stock options (of which 778,665 are vested as of May 31, 2006) to our directors and executive officers for their services, generally exercisable for five years from the date of grant at exercise prices ranging between $1.10 and $10.50.

(2) All option plans previously approved by our shareholders were terminated, and no new option grants may be awarded from those plans, upon adoption on May 3, 2006 of our 2006 Stock and Incentive Plan at a special meeting of our shareholders. As of May 31, 2006, 1,162,000 securities remain available for future issuance under our 2006 plan.

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ITEM 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

THIS DISCUSSION OF THE FINANCIAL CONDITION AND THE RESULTS OF OPERATIONS OF THE COMPANY SHOULD BE READ IN CONJUNCTION WITH, AND IS QUALIFIED 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. We have developed, and are developing, minimally invasive products primarily for the treatment of urinary and fecal incontinence and overactive bladder symptoms. All products we currently sell have received CE marking and are being sold outside the United States in approximately 40 countries, including Europe, Canada, Australia and Latin America. In the U.S. we have received 510(k) clearance for two of our products (I-Stop and Urgent PC). Our Macroplastique and other implantable tissue bulking products have not been cleared for marketing in the United States. We are pursuing FDA approval (PMA) for our Macroplastique product.

Our goal is to develop and commercialize a portfolio of minimally invasive products for the treatment of voiding dysfunctions. We believe that, with a suite of innovative products, we can increasingly garner the attention of key physicians and distributors and enhance market acceptance of our products. The key elements of our strategy are to:

Pursue regulatory approval in the U.S. for our Macroplastique products.

Expand our U.S. marketing and sales organization, using a combination of direct and independent reps;

Conduct multi-center, prospective clinical trials for the Urgent PC;

Expand distribution of our products outside of the U.S.; and

Acquire or license complimentary products if appropriate opportunities arise.

We concluded a multi-center human clinical trial using Macroplastique Implants in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency, a weakening of the muscles that control the flow of urine from the bladder. In December 2004, the FDA accepted for filing our pre-market approval submission with respect to Macroplastique for the treatment of female stress urinary incontinence. This submission is under review by the FDA and we continue to expect, as we indicated in July 2005, the possible approval by the FDA in late 2007. We will incur substantial expenses in connection with these regulatory activities. Even if we obtain regulatory approval, it may be only for limited uses with specific classes of patients, which may limit the market for our product.

In the United States, we recently staffed our sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. We anticipate further increasing, as needed, our sales and marketing organization in the United States 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 primarily through distributors in other markets.

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 market and distribute our products through a network of distributors and through direct sales to end-users in the United Kingdom and The Netherlands. 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 distribution partners purchase the Uroplasty products to meet 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

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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 customer 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.

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. While we expect our sales to grow, a reduction in sales could reduce the demand for our products and may require additional inventory reserves.

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. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders equity.

Impairment of Long-Lived Assets. Long-lived assets at March 31, 2006 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.

Stock Based Compensation and Accelerated Vesting. We accounted for our stock option grants under APB Opinion No. 25 (APB 25), *Accounting for Stock Issued to Employees*, and related interpretations. No stock-based compensation cost is reflected in net loss, as all options granted under these plans had an exercise price equal to the market value of the underlying common stock on the date of grant. We also grant options to non-employees for goods and services and in conjunction with certain agreements. These grants are accounted for under Financial Accounting Standards Board (FASB) Statement No. 123 based on the grant date fair values.

In December 2004, FASB published Statement No. 123 (revised 2004), *Share-Based Payment* (FAS 123(R) or the Statement). FAS 123(R) requires that the compensation cost relating to share-based payment transactions, including grants of employee stock options, be recognized in financial statements. That cost will be measured based on the fair value of the equity or liability instruments issued. FAS 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. FAS 123(R) is a replacement of Statement No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB 25, and its related interpretive guidance.

This Statement will require entities to measure the cost of employee services received in exchange for stock options based on the grant-date fair value of the award, and to recognize the cost over the period the employee is required to provide services for the award. FAS 123(R) permits entities to use any option-pricing model that meets the fair value objective in the Statement. We will be required to apply FAS 123(R) beginning in the first quarter of fiscal year 2007. FAS 123(R) allows two methods for determining the effects of the transition: the modified prospective and the modified retrospective. We have adopted the modified prospective transition method beginning April 1, 2006. The pro forma compensation costs presented previously and in our prior filings have been calculated using a Black-Scholes option pricing model and may not be indicative of amounts which should be expected in future years.

In February 2006, our Board of Directors approved a plan to accelerate, effective February 2, 2006, the vesting of out-of-the-money, unvested stock options previously granted to our employees, officers and directors. An option was considered out-of-

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the-money if the stated exercise price exceeded $2.85, the then closing price of our common stock. We accelerated the vesting of these options to minimize the amount of compensation expense we must recognize upon adoption of SFAS No. 123(R). None of these options had intrinsic value at the acceleration date under APB 25. We expect that the acceleration of the vesting of these options reduced our pre-tax stock option expense by approximately $1.4 million, in the aggregate, calculated using the Black-Scholes option valuation model, that we would otherwise have recognized over the next three fiscal years, upon adoption of SFAS No. 123(R). We do not expect the remaining options, to result in a significant charge to compensation expense upon adoption of SFAS 123(R) under the modified prospective application method. However, certain outstanding options that permit cashless exercise and certain options classified as liabilities could result in a significant charge to compensation expense, as we will mark those options to fair value at each reporting period until settlement. Also, additional options as granted to attract or retain new employees could result in a significant charge to compensation expense.

Income Taxes. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to be applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. We have generated approximately $15,423,000 in U.S. net operating loss carryforwards that cannot be used to offset taxable income in foreign jurisdictions. We recognize a valuation allowance when it is more likely than not a portion of the deferred tax asset will not be realized. We have established a valuation allowance for U.S. and certain foreign deferred tax assets due to the uncertainty that enough income will be generated in those taxing jurisdictions to utilize the assets.

In addition, U..S. tax rules impose limitations on the use of net operating loss following certain changes in ownership change. Such a change in ownership may limit the amount of these benefits that would be available to offset future taxable income each year, starting with the year of ownership change.

Set forth below is management s discussion and analysis of the financial condition and results of operations for the fiscal years ended March 31, 2006 and 2005. See Note 7 to our Consolidated Financial Statements for business segment information.

Results of Operations

Net Sales. In fiscal 2006, net sales of all products were $6.1 million, representing an 8% decrease when compared to net sales of $6.7 million for fiscal 2005. Excluding fluctuations in foreign currency exchange rates, we had a sales decrease of approximately 5% primarily due to a $0.8 million decline in sales of our Macroplastique products offset by a $0.5 million net increase in all of our other products. We attribute this decline primarily to adverse changes in reimbursement policies of the insurers and the increase in pricing competition. We expect these reimbursement changes and the increase in price competition to adversely impact our future sales in those markets. In these markets we have launched a strategy to increase sales of our existing products, and to expand our platform of products for the treatment of voiding dysfunctions. We are conducting training workshops targeted to our sales personnel, distributors and key incontinence surgeons, and we are sponsoring scientific podium presentations and seminars at key international incontinence congresses. We are also seeking to broaden our patient base to include Urgent PC treatment for symptoms of overactive bladder (OAB), the I-Stop sling procedure for treatment of female stress urinary incontinence (SUI) and hypermobility and PTQ Implants and Urgent PC treatments for fecal incontinence. We cannot assure that these initiatives will increase sales.

Gross Profit. Gross profit was $4.3 million and $4.9 million for the fiscal years ended March 31, 2006 and 2005, respectively, or 70% and 74% of net sales. The decline in gross profit percent is attributed primarily to the decline in sales of the above-average gross margin Macroplastique product, and certain one-time costs related to updating our manufacturing quality systems. Gross profit as a percentage of net sales between periods fluctuates based on the following factors: our unit sales, our utilization of manufacturing capacity, the mix of products sold with different gross margins, the mix of customers (and different discounts to them), the mix of direct sales versus sales through distributors (with higher margins on direct sales), and currency fluctuations. Historically, our gross margin has ranged from approximately 70-80% of net sales.

General and Administrative Expenses. General and administrative (G&A) expenses increased from $2.3 million during fiscal 2005 to $3.0 million during fiscal 2006. The increase in expense is attributed to: $590,000 increase in

salary costs, including $150,000 for severance pay and $100,000 option expense for former executives, $170,000 increase in information (IT) expense, $100,000 increase in legal and accounting fees, $80,000 increase in recruiting costs, $50,000 of expenses related to listing the company on the American Stock exchange, $110,000 increase in depreciation and amortization expense, general price increases and fluctuations in foreign currency exchange rates, offset by a decrease in bad debt expense of $330,000. The IT consulting expense relates to the implementation of a new computer software system, including training and post-implementation support.

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Research and Development Expenses. Research and development expenses increased 47% from $2.3 million during fiscal 2005 to $3.3 million during fiscal 2006. The increase in expense is attributed to a $350,000 increase in salary costs, including $170,000 for severance pay to a former executive, and $770,000 for consulting expense for product development and regulatory approvals, offset by a $130,000 reduction in costs for clinical trials and testing.

Selling and Marketing Expenses. Selling and marketing expenses increased 69% from $2.0 million during fiscal 2005 to $3.4 million during fiscal 2006. The increase in expenses is attributed to $940,000 for expansion of our direct sales force and marketing organizations in the U.S., $190,000 for increase in costs for travel, trade-shows and conventions, $90,000 for increase in consulting expense, and general price increases and fluctuations in foreign currency exchange rates.

Other Income (Expense). Other income (expense) includes interest income, interest expense, warrant expense or benefit, foreign currency exchange gains and losses and other non-operating costs when incurred. Our financial results are subject to material fluctuations based on changes in currency exchange rates. Other income (expense) was $788,597 and $(11,510) for fiscal 2006 and fiscal 2005, respectively.

In July 2002, we conducted a rights offering pursuant to which our stockholders purchased certain units consisting of shares of our common stock and common stock purchase warrants exercisable for two years at $2.00 per share. However, we suspended the exercise of the warrants when we delayed the filing of our annual report on Form 10-KSB for the fiscal year ended March 31, 2004. As a result, 706,218 of the warrants lapsed unexercised at July 31, 2004. In April 2005, we granted a like number of new common stock purchase warrants to the holders of the expired warrants. The new warrants will be exercisable at $2.00 per share for 90 days after the effective date of a new registration statement covering the resale of the shares underlying these warrants. We have filed a registration statement covering such warrants on Form SB-2 with the Securities and Exchange Commission (SEC). In April 2005, we recognized a liability and equity charge of $1.4 million associated with the grant of these warrants. A net warrant benefit of $707,320 for fiscal 2006 is included in the statement or operations which represents the change in the fair value of the warrants since their issuance due to the change in value of the common stock which may be acquired by the exercise of these warrants.

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between us and our foreign subsidiaries. We recognized foreign currency losses of $31,195 and $15,744 for fiscal 2006 and fiscal 2005, respectively.

Income Tax Expense. Our Dutch subsidiaries recorded income tax expense (benefit) of $(46,873) and $91,503 for fiscal 2006 and fiscal 2005, respectively. We cannot use the U.S. net operating loss carry forwards to offset taxable income in foreign jurisdictions. For fiscal 2006, the Dutch income tax rate was 25.5% for 22,689 (approximately $27,500) of profit and 29.6% for amounts above 22,689 compared to 27% and 31.5% in fiscal 2005, respectively.

Liquidity and Capital Resources

Cash Flows. As of March 31, 2006, our cash and cash equivalent and short-term investments balances totaled $2.7 million.

At March 31, 2006, we had working capital of approximately $2.7 million. In fiscal 2006, we used $4.6 million of cash in operating activities, compared to $1.3 million of cash used in the same period of fiscal 2005. The usage of cash was primarily attributable to the net loss incurred of $4.5 million. Inventory increased by $280,000, due to production planning requirements, manufacturing lead times and the introduction of additional products. Accounts receivable, other current assets, accounts payable and accrued expenses fluctuated due to the timing of payments and fluctuations in foreign currency exchange rates.

Fluctuations in foreign currency exchange rates, weak economic conditions in foreign markets where we sell and distribute our products, changes in regulatory environment and changes in third-party reimbursement polices could materially affect our financial condition and results of operations. The effects of these conditions could include reduced unit sales and reduced sales in dollars when converted from foreign currency amounts and material gains and losses on transactions denominated in foreign currencies. Furthermore, because our U.S. operations are funded by sales denominated in foreign currency, strengthening of the U.S. dollar against the euro and/or the British pound could have an adverse effect on our cash flow and results of operations.

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Sources of Liquidity. In April 2005, we conducted a private placement of common stock in which we sold 2,147,142 shares of our common stock at a price per share of $3.50, together with warrants to purchase 1,180,928 shares of common stock, for an aggregate purchase price of approximately $7.5 million. The stock sale proceeds are offset by costs of approximately $935,000, resulting in net proceeds of approximately $6.6 million. The warrants are exercisable for five years at an exercise price of $4.75 per share.

In connection with our April 2005 private placement, we agreed to file a registration statement with the SEC covering the resale of the shares (including those underlying the warrants) that we sold. We also agreed that, for each month after May 21, 2005, that we failed to file this registration statement, and for each month after July 20, 2005 that the SEC did not declare it effective, we would pay liquidated damages at a rate of 1% of the aggregate investment. We filed the registration statement on July 20, 2005 and the SEC declared it effective on July 29, 2005. Accordingly, in January 2006, as settlement of liquidated damages and interest in the amount of $174,054, we issued 57,381 shares of our common stock and paid cash in the amount of $23,077.

Commitments and Contingencies. We believe that our current resources, funds generated from sale of our products and remaining proceeds from the private placement completed earlier this year together with the recent credit facilities (see Note 9, Subsequent Events, to the financial statements) will be adequate to meet our cash flow needs, including regulatory activities associated with existing products, through the end of the next fiscal year. We will need to raise additional debt or equity financing to continue funding for product development and continued expansion of our sales and marketing activities, and ultimately, we will need to achieve profitability and generate positive cash flows from operations to fund our operations and grow our business. As such we plan to raise additional equity capital in fiscal 2007, but there can be no guarantee that we will be successful. In the event that such required financing is not immediately available, management is prepared to curtail planned product development activities and other expenditures to ensure adequate working capital is available through fiscal 2007.

We expect to continue to incur significant costs for regulatory activities associated with obtaining regulatory approval in the United States for Macroplastique. For fiscal 2007, we expect to incur significant research and development expenses, including those in connection with the regulatory approval activities for Macroplastique. We also expect that during fiscal 2007, we will continue to incur significant expenses as we expand our selling and marketing organization in the U.S. to market our products. In addition, we expect general and administrative expenses in fiscal 2007 to increase as we increasingly prepare to implement the provisions of Section 404 of the Sarbanes-Oxley Act of 2002.

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix for the Urgent PC product. The agreement required us to pay CystoMedix an initial payment of $225,000 and an additional payment of $250,000 in 12 monthly installments of $20,833. We capitalized the aggregate amount as licensed technology and are amortizing it over the term of the agreement. We will also pay CystoMedix a 7% royalty on product sales. However, the 7% royalty is first offset against the monthly royalty installments.

CystoMedix has also granted us an exclusive option to acquire its assets. The purchase price is $3,485,000, reduced by up to $50,000 of liabilities assumed by us. However, the $3,485,000 amount used to compute the purchase price will increase at a rate of 10% per year after April 2007. The purchase price is payable in shares of our common stock valued at the average of the closing bid price of our shares for the 20 trading days prior to our exercise of the option. We may exercise the option between January 2006 and June 2008. If we exercise the option, we will also assume up to $1.4 million of bridge loan advances made to CystoMedix by its Chairman. We would repay up to $1.1 million of the bridge loan advances at closing and would issue our common stock for the balance of the bridge loan based on the above option price. We also have certain rights of first refusal to acquire CystoMedix s assets in the event CystoMedix receives a third party offer in advance of any exercise of our option. We will need to raise additional equity or debt funds in order to consummate the CystoMedix acquisition, should we elect to do so.

We have two exclusive distribution agreements with CL Medical allowing us to market and sell the I-Stop urethral sling: effective February 2006, a six-year agreement, with a right to renew it for successive five-year terms, for distribution in the United States and, effective May 2005, a one-year agreement with automatic renewal for up to two years, for distribution the in United Kingdom. Under the agreements, we are required to purchase a minimum of $630,000 of units in the first 12-month period following January 1, 2006, increasing to $2.6 million of units in the

fifth year of the agreement, for an aggregate commitment of approximately $6.7 million of units over the five-year period, subject to periodic adjustment based on the value of the euro.

We are obligated to pay royalties of 5% of net sales of Macroplastique products in the U.S. with a minimum of $50,000 per year. The duration of this royalty agreement is through May 1, 2006. Under another 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

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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.

We have a pension plan covering 16 employees in The Netherlands, reported as a defined benefit plan. 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 also closed our UK subsidiary s defined benefit plan to further accrual for all employees effective December 31, 2004. In March 2005, the UK subsidiary established a defined contribution plan that now covers new employees.

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 estimated to be approximately $82,000 in the first 12 months.

On May 31, 2006, we entered into a promissory note with Venture Bank with a principal amount of $100,000, interest rate of 8.25% per annum, and a maturity date of May 31, 2009. The amount is used for certain capital expenditures relating to the relocation of our facility to our Minnetonka, Minnesota location.

Repayments of our contractual obligations as of March 31, 2006, consisting of royalties, notes payable (inclusive of interest), and operating leases, including the January 20, 2006 lease noted above, are summarized below:

	Payments Due by Period				
	Total	Fiscal 2007	Fiscal 2008 and 2009	Fiscal 2010 and 2011	Fiscal 2012 and thereafter
Minimum royalty payments	$ 318,333	$ 124,833	$ 108,000	$ 85,500	$
Minimum purchase agreement	6,676,416	735,283	2,016,715	3,924,418	
Notes payable	655,665	92,087	187,212	102,468	273,898
Operating lease commitments	1,445,492	327,768	394,824	285,773	437,127
Total contractual obligations	$ 9,095,906	$ 1,279,971	$ 2,706,751	$ 4,398,159	$ 711,025

Recent Accounting Pronouncements

Statement of Financial Accounting Standards 154, Accounting Changes and Error Corrections

In May 2005, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, 154, *Accounting Changes and Error Corrections*. This new standard replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*. Among other changes, Statement 154 requires retrospective application of a voluntary change in accounting principle with all prior period financial statements presented on the new accounting principle, unless it is impracticable to do so. Statement 154 also requires accounting for a change in method of depreciating or amortizing a long-lived nonfinancial asset as a change in estimate (prospectively) affected by a change in accounting principle. Further, the Statement requires that correction of errors in previously issued financial statements be termed a restatement. The new standard is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. Early adoption of this standard is permitted for accounting changes and correction of errors made in fiscal years beginning after June 1, 2005. We do not believe the adoption of FASB Statement 154 will have a material effect on our financial position or results of operations.

Statement of Financial Accounting Standards 151, *Inventory Costs*

In November 2004, the FASB, issued SFAS 151, *Inventory Costs, An Amendment of Accounting Research Bulletin No. 43, Chapter 4,* which adopts wording from the International Accounting Standards Board s, or IASB, IAS 2

Inventories in an effort to improve the comparability of cross-border financial reporting. The new standard requires us to treat abnormal freight, handling costs and wasted materials (spoilage) as current period charges rather than as a portion of inventory cost. Additionally, the standard clarifies that we should allocate fixed production overhead based on the normal capacity of a

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production facility. The statement is effective for us beginning in fiscal 2007. We do not expect adoption to have a material impact on our consolidated financial statements.

Statement of Financial Accounting Standards 123(R), *Share-Based Payment*

In December 2004, the FASB issued SFAS 123(R), *Share-Based Payment*, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation,* and supersedes APB Opinion 25, *Accounting for Stock Issued to Employees.* SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be valued at fair value on the date of grant, and to be expensed over the applicable vesting period. SFAS 123(R) is effective for us beginning on April 1, 2006. Please refer to discussion in Stock Based Compensation and Accelerated Vesting under critical account policies.

Financial Accounting Standards Board Interpretation No. 47

In March 2005, the FASB issued FASB Interpretation No.47, or FIN 47, which clarifies terminology in FASB Statement No. 143, *Accounting for Asset Retirement Obligations*. FIN 47 clarifies when an entity has sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 was effective for us in fiscal 2006. Adoption of FIN 47 did not have a material impact on our consolidated financial statements.

ITEM 7. FINANCIAL STATEMENTS

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

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 8A. CONTROLS & PROCEDURES

Disclosure Controls and Procedures. As of the end of the period covered by this report, we conducted an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of our disclosure controls and procedures as defined in Rules 13(a)-15(e) under the Securities Exchange Act of 1934 (the Exchange Act). Based on this evaluation, the principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Internal Control Matters. We also maintain a system of internal accounting controls designed to provide reasonable assurance that our books and records accurately reflect our transactions and that our policies and procedures are followed. There have been no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2006, or thereafter, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

In connection with our review of our consolidated financial statements for the year ended March 31, 2005 and the audit of those statements by our independent registered public accounting firm, we determined that our year-end financial statement closing process did not ensure our adequate review of all significant elements of our consolidated financial statements. In our post-closing and audit processes, we and our independent registered public accounting firm discovered certain issues that resulted in adjustments to our consolidated financial statements, specifically with respect to our inventory valuation and income tax provision. We discovered these matters before our consolidated financial statements were completed, and they are properly accounted for in our financial statements. However, we have concluded that the failure to discover these items in our regular closing process is a result of a significant deficiency, resulting primarily from a lack of segregation of duties due to the size of our company and the geographic distance between our key financial personnel, that constitutes a material weakness in the design or operation of our internal controls over financial reporting.

A significant deficiency is defined as a control deficiency, or combination of deficiencies, that adversely affects a company s ability to initiate, authorize, record, process or report external financial data reliably in accordance with

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generally accepted accounting principles such that there is more than a remote likelihood that a misstatement of the company s financial statements that is more than inconsequential will not be prevented or detected.

A material weakness is a significant deficiency, or combination of significant deficiencies, that result in more than a remote likelihood that a material misstatement of the financial statements will not be prevented or detected.

Although the items described above were properly accounted for before completing our consolidated financial statements for fiscal year 2005, we have concluded that the failure to discover these items in our regular closing process was a material weakness because the elements of our consolidated financial statements that were not adequately reviewed are material to our consolidated financial statements and there is more than a remote likelihood that a material misstatement of our consolidated financial statements would not be prevented or detected.

We discussed the material weakness described above with our Audit Committee. We have implemented corrective actions where required to improve the effectiveness of our internal controls, including the enhancement of our systems and procedures. Specifically, we have enhanced and formalized our period-end closing processes to ensure we adequately review all significant elements of our consolidated financial statements.

Any control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of a control system inherently has limitations, and the benefits of controls must be weighed against their costs. Additionally, 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.

ITEM 8B. OTHER INFORMATION

None.

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PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

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

ITEM 10. EXECUTIVE COMPENSATION

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

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

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

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

ITEM 13. EXHIBITS AND REPORTS

(a) Exhibits incorporated by reference.

Number	Description
2.1	First Amended Joint Plan of Reorganization (Modified) dated January 31, 1994 (Incorporated by reference to Exhibit 8.1 to Registrant s Registration Statement on Form 10SB)
3.1	Articles of Incorporation of Uroplasty, Inc. (Incorporated by reference to Exhibit 2.1 to Registrant s Registration Statement on Form 10SB)
3.2	Bylaws of Uroplasty, Inc. (Incorporated by reference to Exhibit 2.2 to Registrant s Registration Statement on Form 10SB)
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)
4.2	Form of Warrant (Incorporated by reference to Exhibit 4.2 to Registrant s Registration Statement on Form SB-2, Registration No. 333-128313)
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)
10.2	Purchase and Sale Agreement dated December 1, 1995 by and among Bio-Vascular, Inc., Bioplasty, Inc., and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.2 to Registrant s Registration Statement on Form 10SB)
10.3	License Agreement dated December 1, 1995 by and between Bio-Vascular, Inc. and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.3 to Registrant s Registration Statement on Form 10SB)
10.4	Lease Agreement dated January 10, 1995 between Summer Business Center Partnership and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.4 to Registrant s Registration Statement on Form 10SB)

10.5	Unsecured $640,000 Promissory Note dated March 30, 1994 by and between Bioplasty, Inc., Uroplasty, Inc. and Bioplasty Product Claimants Trust (Incorporated by reference to Exhibit 6.5 to Registrant s Registration

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Number	Description
	Statement on Form 10SB)
10.6	Agreement and Satisfaction dated January 30, 1995 by and between Bioplasty Product Claimants Trust and Bioplasty, Inc. (Incorporated by reference to Exhibit 6.6 to Registrant s Registration Statement on Form 10SB)
10.7	Asset Sale and Satisfaction of Debt Agreement dated June 23, 1995 by and between Bioplasty, Inc. and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.7 to Registrant s Registration Statement on Form 10SB)
10.8	Executory Contract Assumption Stipulation dated December 28, 1993 by and between Bioplasty, Inc., Uroplasty, Inc., and Collagen Corporation (Incorporated by reference to Exhibit 6.8 to Registrant s Registration Statement on Form 10SB)
10.9	Settlement and License Agreement dated July 23, 1992 by and between Collagen Corporation, Bioplasty, Inc., and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.9 to Registrant s Registration Statement on Form 10SB)
10.10	Employment Agreement between Uroplasty, Inc. and Christopher Harris dated December 7, 1999. (Incorporated by reference to Exhibit 10.11 to Registrant s Form 10-KSB for the year ended 03-31-2000.)
10.11	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 03-31-2000.)
10.12	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 03-31-2000.)
10.13	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 03-31-2001)
10.14	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 03-31-2003)
10.15	Consulting Agreement between Uroplasty, Inc. and CCRI Corporation dated April 1, 2003. (Incorporated by reference to Exhibit 10.18 to Registrant s Form 10-KSB for the year ended 03-31-2003)
10.16	Form of Manufacturing and Distribution Agreement with CL Medical SAS (Incorporated by reference to Exhibit 10.19 to Registrant s Form 10-QSB for the period ended September 30, 2004)
10.17	

	Employment Agreement between Uroplasty, Inc. and Sam B. Humphries dated January 1, 2005 (Incorporated by reference to Exhibit 10.1 to Registrant s Form 10-QSB for the period ended December 31, 2004)
10.18	Employment and Consulting Agreement between Uroplasty, Inc. and Daniel G. Holman dated January 1, 2005 (Incorporated by reference to Exhibit 10.2 to Registrant s Form 10-QSB for the period ended December 31, 2004)
10.19	Exclusive Manufacturing and Distribution Agreement, dated as of April 18, 2005, by and between Uroplasty, Inc. and CystoMedix, Inc. (Incorporated by reference to Exhibit 10.19 to Registrant s Form 8-K dated April 18, 2005)
10.20	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 dated April 21, 2005)
10.21	Form of Warrant (Incorporated by reference to Exhibit 10.21 to Registrant s Form 8-K dated April 21, 2005)
10.22	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 Form 8-K dated April 21, 2005)
10.23	Business Loan Agreement and related Promissory Note dated March 24, 2005 with Venture Bank (Incorporated by reference to Exhibit 10.26 to Registrant s Form 10-KSB for the year ended March 31, 2005)

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Number	Description
10.24	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 for the period ended September 30, 2005)
10.25	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 dated January 24, 2006)
10.26	Form of Distribution Agreement between Uroplasty, Inc. and CL Medical SARL, dated February 15, 2006 (Incorporated by reference to Exhibit 10.26 to Registrant s Form SB-2/A dated February 21, 2006
10.27	Letter Agreement between Daniel G. Holman and Uroplasty, Inc., amending terms of Employment Agreement dated January 1, 2005 (Incorporated by reference to Exhibit 10.26 to Registrant s Form 8-K dated March 27, 2006)
10.28	Letter Agreement pursuant to separation arrangements between Sam B. Humphries and Uroplasty, Inc., dated April 26, 2006 (Incorporated by reference to Exhibit 10.28 to Registrant s Amendment No. 1 to Form SB-2 dated April 27, 2006).
10.29	Letter Agreement between Uroplasty, Inc. and Daniel G. Holman dated April 26, 2006 (Incorporated by reference to Exhibit 10.29 to Registrant s Amendment No. 1 to Form SB-2 dated April 27, 2006).

(b) The following exhibits are filed as part of this report:

Number	Description
10.30	Employment Agreement between Uroplasty, Inc. and David B. Kaysen dated May 17, 2006.
10.31	Business Loan Agreement and related Promissory Note dated May 31, 2006 with Venture Bank
13	Financial Statements
21.0	List of Subsidiaries
23.1	Consent of Independent Registered Public Accounting Firm McGladrey & Pullen, 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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information contained under the heading Independent Registered Public Accounting Firm in the Proxy Statement is incorporated herein by reference.

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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 29, 2006

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	President, Chief Executive Officer and Director	
David B. Kaysen	(Principal Executive Officer)	June 29, 2006
/s/ Mahedi A. Jiwani	Vice President, Chief Financial Officer	
Mahedi A. Jiwani	and Treasurer (Principal Financial and Accounting Officer)	June 29, 2006
/s/ Arie J. Koole		
Arie J. Koole	Controller	June 29, 2006
/s/ Sam B. Humphries		
Sam B. Humphries	Director	June 29, 2006
/s/ Joel R. Pitlor		
Joel R. Pitlor	Director	June 29, 2006
/s/ R. Patrick Maxwell		
R. Patrick Maxwell	Director	June 29, 2006
/s/ Thomas E. Jamison		
Thomas E. Jamison	Director	June 29, 2006