UROPLASTY INC
Form 10KSB
June 29, 2005

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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, 2005

Commission File No. 000-20989

UROPLASTY, INC.

(Name of Small Business Issuer in its Charter)

Minnesota, U.S.A.	**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 NO o

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

Issuer s revenues for its most recent fiscal year: $6,657,726

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, 2005 was $18,023,072.

The number of shares outstanding of the issuer s only class of common stock on June 1, 2005 was 6,846,739.

Documents Incorporated By Reference: Portions of the Company s Proxy Statement for its 2005 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 NO þ

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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, 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. Products we market and have under development include our Macroplastique® urethral bulking agent, the I-Stop tape and the Urgent® PC neurostimulation system.

Macroplastique® Implants, our key product, is a proprietary, implantable soft tissue bulking product 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 muscles 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 for urological indications outside the United States since 1991. 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.

The I-Stop tape is a biocompatible, tension-free sling for the treatment of stress urinary incontinence resulting from urethral hypermobility, a condition in which the urethra is not properly supported by surrounding tissues. We are the exclusive distributor of the product in the United Kingdom and, subject to FDA marketing clearance, in the U.S. where we plan to establish an assembly operation.

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 the product for the U.S., Canada and all countries recognizing the CE mark. We do not yet sell the Urgent PC system.

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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, I-Stop and Urgent PC products.

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

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

Acquire or license complimentary products if appropriate opportunities arise.

In furtherance of our first key strategy above, we are concluding a multi-center human clinical trial using Macroplastique in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency. This is the weakening of the muscles that control the flow of urine from the bladder. We recently filed a pre-market approval (PMA) submission with the FDA describing Macroplastique use for this indication. For the I-Stop tape, we plan to submit to the FDA a 510(k) pre-market notification application in 2005. We are also responsible for obtaining and/or maintaining FDA and foreign regulatory approvals for the Urgent PC system. Although the Urgent PC device currently has U.S. pre-market clearance, we intend to file our own 510(k) pre-market notification application in 2005 for the version of the device we intend to sell.

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 incontinence (management and curative approaches) of all types in the United States as $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.

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.

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Types of Urinary Incontinence

There are four types of urinary incontinence:

Stress Urinary Incontinence - Stress urinary incontinence, or SUI, refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from ordinary physical activities, such as coughing, sneezing, laughing, straining or lifting. 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 valve or 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 neurologic problems cause the bladder to contract and empty with little or no warning.

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

Mixed Incontinence - Mixed incontinence is the combination of both urge and stress incontinence (and, in some cases, overflow). 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 items such as pads or diapers. The other approach is to undergo curative treatments in an attempt to restore continence, such as injection of urethral 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.

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, may be a closed, indwelling system, or may be external collection devices.

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 seldom cure stress urinary incontinence. Common side effects 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.

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Curative Treatment of Urinary Incontinence

Injectable Bulking Agents. Urethral bulking agents are inserted with a needle into the area around the urethra, augmenting the surrounding tissue for increased capacity to control the release of urine. Hence, these materials are often called bulking agents or injectables. Urethral bulking agents may be either synthetic or biologically derived and are an attractive alternative to surgery because they are considerably less invasive. 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 will be 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 main surgical option is 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. 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, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site. This reduces the need for follow-up treatments. Additionally, there is no need for special storage, cumbersome preparation or mixing for use, nor is there a

need for patient allergy testing.

We currently market Macroplastique outside the U.S. on the basis that our outpatient, minimally invasive treatment can lead to lower surgical risk with shorter recovery time, and that it is less expensive when compared to invasive alternatives. Its safety and efficacy are evidenced by 14 years of successful use outside the United States with over 50,000 patients treated. Recently, we filed a pre-market approval submission with the U.S. FDA for domestic marketing of Macroplastique for the treatment of adult female stress incontinence.

Although Macroplastique is traditionally implanted with the aid of an endoscope, we also market outside the United States a patented, non-endoscopic 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. Following FDA approval of Macroplastique, we intend to seek regulatory approval for the MIS.

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I-Stop Sling

In May 2004, we became the exclusive distributor in the United Kingdom of the I-Stop tape, a biocompatible, tension-free, mid-urethral sling manufactured by CL Medical SAS of Lyon, France. This CE marked device, which is sold in Europe, is 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 become too moveable and 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.

We believe that the I-Stop product is the only synthetic, mid-urethral sling made of monofilament knitted polypropylene with closed loop edges, making 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.

In September 2004, we entered into a manufacturing and distribution agreement with CL Medical under which we have expanded our relationship to become the exclusive distributor of the I-Stop sling in the United States. The I-Stop product is not approved by the FDA for sale in the U.S. We are responsible for FDA clinical and regulatory requirements for the I-Stop sling, and for assembly, sterilization, packaging and labeling of the product for the U.S. market. With the technology transfer, we expect to submit to the FDA a 510(k), or pre-market notification application, with respect to the I-Stop sling in 2005.

The manufacturing and distribution agreement is for six years, with our right to renew it for successive five-year terms. We have agreed to purchase our entire requirement of product components from CL Medical. Contingent on U.S. FDA clearance of the product for U.S. sale, we also have specified minimum purchase requirements of $240,000 of units in the first year thereafter, increasing to approximately $1.9 million of units over a five year period, subject to periodic adjustment based on the value of the Euro. CL Medical will provide us with any improvements it makes to the I-Stop sling without additional charge. In addition, CL Medical has granted us a right of first refusal for exclusive manufacturing, assembly and/or distribution rights in the United States to any new medical devices or procedures it develops during the term of our agreement. In return, we have agreed that during, and for three years after, the term of our 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.

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.

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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, to license the exclusive rights to manufacture and market the Urgent® PC device 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 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 followup treatments as required to maintain symptom reduction.

CystoMedix obtained approval to affix the CE mark on the Urgent PC device and began marketing it in Europe during 2003. The Urgent PC is also cleared for sale in the United States. Under our agreement with CystoMedix, we are responsible for regulatory applications and compliance within all markets outlined in the agreement. We plan to seek our own CE mark approval, and, although the Urgent PC currently has U.S. pre-market clearance, we intend to file our own 510(k) application in 2005 for the version of the device we intend to sell.

Our agreement with CystoMedix is for five years, with no right to renew it. In connection with the agreement, 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 are paying an additional aggregate of $250,000 in royalties in monthly installments through May 2006. During the agreement s term, we also 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 amount. We have 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.

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. However, the $3,485,000 amount used to compute the option price will increase at a rate of 10% per year after April 2007. 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 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.

The Problem of Fecal Incontinence

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

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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.

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 market and sell Macroplastique and related ancillary products, and the I-Stop sling, only in countries outside the United States. We have a direct sales force in the United Kingdom. International sales managers in The Netherlands manage and train a network of distributors selling our Macroplastique and related products in approximately 40 countries, including Canada, Australia, countries within Europe and Latin America, and the I-Stop sling in the United Kingdom. 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 70% and 66% of total net sales for fiscal 2005 and 2004, respectively. When the FDA approves our products, we will expand our sales and marketing organization to support U.S. sales.

We use clinical studies and scientific community awareness programs to demonstrate the safety and efficacy of our products. This data is important to obtain regulatory approval and to support our sales staff and distributors in securing product reimbursement in their territories. Publications of clinical data in peer-reviewed journals add to the scientific community awareness of our products, including patient indications, treatment technique and expected outcomes. 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 recent clinical trials to provide outcome evidence on new products recently developed by us. These include randomized controlled clinical trials on our PTQ Implants and clinical studies on the Macroplastique Sling Support Kit (MIS-SK). 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. Components are manufactured in the United States, and finished products are manufactured in The Netherlands. Our facilities utilize dedicated heating, ventilation and high

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efficiency particulate air (HEPA) filtration systems to provide a controlled working environment. Trained production technicians perform all critical manufacturing processes in a cleanroom environment according to established written procedures. An outside vendor sterilizes our products using validated methods and returns the products to us for final inspection and testing.

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. Prior to marketing our products in the United States, we will also be inspected by the FDA for compliance with U.S. federal Quality System Regulations and will be subject to additional state, local, and federal government regulations applicable to the manufacture of our products.

CL Medical in Lyon, France manufactures the I-Stop sling. Pursuant to the manufacturing and distribution agreement with CL Medical, we are required to purchase all of our product component requirements from CL Medical. Contingent on U.S. FDA clearance of the product for U.S. sale, we also have specified minimum purchase requirements of $240,000 of units in the first year thereafter, increasing to approximately $1.9 million of units over a five year period, subject to periodic adjustment based on the value of the Euro. We are required to establish our own manufacturing facility or to outsource to a third party the assembly of the final product and sterilization, packaging and labeling of the finished product. The agreement has an initial term of six years, with successive five-year renewal terms at our option.

Under our manufacturing and distribution agreement with CystoMedix, Inc., we will be responsible for establishing our own manufacturing facility or for subcontracting the manufacture of the Urgent PC device. We currently expect to subcontract the manufacture of major subassemblies for the product.

We purchase medical grade materials for use in our finished products from single source suppliers. Our quality department has qualified these suppliers. Although we believe our sources of supply 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. In fact, one of the suppliers of a component material of our Macroplastique product recently ceased production of this material. We have located an alternative supplier.

Competition

The market for voiding dysfunction products is intensely competitive. We face competition from existing manufacturers of management and curative treatments, competing manufacturers of commercially available bulking agents, sling products and neurostimulation devices, drug companies and firms developing new or improved treatment methods. We believe the principal competitive factors among treatment methods include physician and patient acceptance of the method in managing or curing incontinence, cost and availability of third-party reimbursement, marketing and sales capability and the existence of meaningful patent protection. Our ability to compete in this market will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors within and outside our control 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. In contrast to the products currently approved for sale both inside and outside this country, Macroplastique, marketed outside the United States since 1991, is a synthetic material that will not degrade, become resorbed or migrate, 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 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 the I-Stop sling offers benefits of multiple surgical approaches for the physician and a design to resist stretching, deformity (i.e., preventing the cord effect) and fragmentation.

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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.

Many medications treat urge incontinence, 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 urine buildup. 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 us. In addition, many of our competitors offer broader product lines within the urology market, which may give these competitors the ability to negotiate exclusive, long-term supply contracts and to offer comprehensive pricing for their products. It is possible other large health care and consumer products companies may enter this industry in the future. Furthermore, smaller companies, academic institutions, governmental agencies and other public and private research organizations will continue to conduct research, seek patent protection and establish arrangements for commercializing products. These products may compete directly with any products that we may offer in the future.

Government Regulation

The testing, manufacturing, promotion, marketing and distribution of our products in the United States, Europe and other parts of the world are subject to regulation by numerous governmental authorities, including the 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, or FDC Act. Noncompliance with applicable requirements can result in, among other things:

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, or total or partial suspension of production;

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

withdrawal of existing approvals; and

criminal prosecution.

Depending on the degree of risk posed by the medical device and the extent of controls needed to ensure safety and effectiveness, there are two pathways for FDA marketing clearance of medical devices. For devices deemed by FDA to pose relatively less risk (Class I or Class II devices), manufacturers, in most instances, must submit a pre-market notification requesting permission for commercial distribution; known as 510(k) clearance. Devices deemed by 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 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

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the device will require a new 510(k) pre-market notification submission or 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 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 changes from the device covered by the original pre-market approval application, and may not require as extensive clinical data 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; and

- notices of correction or removal, and recall regulations.

FDA Approval Status of Our Products. The FDA has determined that urethral blocking 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 with respect to Macroplastique for the treatment of stress urinary incontinence. In 2000, we commenced a human clinical trial at multiple sites. We have concluded the 12-month patient follow up visits for this study, recently submitted a pre-market approval application with respect to Macroplastique and await final

24-month follow up visits on Macroplastique patients.

We expect and believe the I-Stop sling is eligible for 510(k) clearance based on its substantial equivalence to previously legally marketed devices in the U.S. We plan to file a 510(k) application with the FDA for the I-Stop sling during 2005. However, we cannot guarantee that the FDA will agree with our view that the I-Stop sling is eligible to use the 510(k) clearance process or that the FDA will not request additional information to support 510(k) clearance. A not substantially equivalent determination or request for additional data could prevent or delay the market introduction of the I-Stop sling, which in turn could have a material adverse effect on our potential revenues.

The Urgent PC device previously received 510(k) clearance for U.S. marketing by the FDA. However, we plan to file our own 510(k) pre-market application during 2005 for the version of the product that we intend to sell in the United States.

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FDA Oversight of Manufacturing Operations. The FDA Act requires that medical devices be 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 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 VOX in 2000 for vocal cord rehabilitation applications; for PTQ in 2002 for the treatment of fecal incontinence; and for Bioplastique in 1996 for dermal augmentation applications. Our manufacturing facilities and processes have been inspected and certified by AMTAC Certification Services, a recognized Notified Body, testing and certification firm based in the United Kingdom. The I-Stop sling received CE marking approval in July 2002. CystoMedix, the company that granted us rights to manufacture and distribute the Urgent PC nerve stimulation device, also obtained its own CE mark. As we transition this product to our company, we anticipate applying for our own CE mark approval for the Urgent PC device.

We currently sell our products in about 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 such as those produced by us are increasing worldwide. We anticipate that this trend will continue and that the cost and time required to obtain approval to market in any given country will increase.

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 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;

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

payment amount.

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We believe that coding, coverage and payment issues for tension-free sling products have been addressed by numerous competitors. However, we will need to determine if reimbursement for the I-Stop product will require any modifications of coding, coverage or payment policies. It appears that appropriate codes are available to describe endoscopic use of Macroplastique to treat female SUI, but coding will need to be confirmed. 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. As a relatively new therapy, PTNS using the Urgent PC is not adequately described by existing codes. We will need to provide customer reimbursement support during our launch and early growth, seek coverage policies, secure market acceptance and support advocacy to secure new coding for this procedure. There is no uniform policy for reimbursement throughout the United States and no guarantee Macroplastique, the I-Stop sling or the Urgent PC device 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 patentable technologies we consider important to the development of our business based on an analysis of the cost of obtaining a patent, the likely scope of protection and the relative benefits of patent protection compared to trade secret protection, among other considerations.

We 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.

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 of $50,000 per year. The agreement is through May 1, 2006.

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 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® 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. CystoMedix has U.S. registration of the Urgent®PC trademark and has licensed the mark to 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 potential improvements as well as new methods and devices for the implantation of Macroplastique and on new applications for this material. Research and development expenses also include the costs of clinical studies and

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regulatory compliance. Our expenditures for research and development totaled $2.3 and $1.8 million for fiscal 2005 and 2004, 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 2005 and 2004 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During fiscal 2005, two customers accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% and 11% of our net sales.

Employees

As of March 31, 2005, we had 45 employees, of which 37 were full-time and 8 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, is the manufacturer of Macroplastique, Bioplastique, VOX Implants, PTQ Implants and of all their accessories, and sells its products through distributors.
Uroplasty LTD	Incorporated in the United Kingdom and acts as the sole distributor of Macroplastique, Bioplastique, PTQ Implants, all of their accessories, and wound care products in the United Kingdom and Ireland.
Bioplasty BV	Incorporated in The Netherlands and is the distributor of Bioplastique to subdistributors, and distributes wound care products in The Netherlands.

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 have incurred significant operating losses and we may not achieve or maintain profitability in the future.

We have incurred net losses in each of the last five fiscal years. As of March 31, 2005, we had an accumulated deficit of approximately $6.5 million primarily as a result of costs relating to the development and commercialization of our Macroplastique and related products. We expect our operating expenses relating to sales and marketing activities and

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product development, including seeking U.S. regulatory approvals for Macroplastique and the I-Stop and Urgent PC products, 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, the I-Stop sling and the Urgent PC device, and our ability to achieve widespread market acceptance for those 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, the I-Stop sling or the Urgent PC device 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. We cannot predict if or when we will receive pre-market approval for Macroplastique. Even if we obtain regulatory approval, approval may be only for limited uses with specific classes of patients, which may limit the market for our product.

We believe that the I-Stop sling and the Urgent PC nerve stimulation device will be eligible for U.S. marketing clearance through the pre-market notification process under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or the FDC Act, based on these products substantial equivalence to previously legally marketed devices in the U.S. However, we cannot assure you that the FDA will agree with our determination that these products are eligible for the Section 510(k) pre-market notification process or that the FDA will not request additional information to support 510(k) clearance. If the FDA requires us to go through a lengthier, more rigorous examination than we expect, our product introductions or modifications could be delayed or canceled, which could adversely affect our sales. We cannot guarantee that the FDA will timely, if at all, clear either of these products for our sale.

To market our products in Europe, they must be approved to affix the CE mark. We cannot assure when, or if, we will be able to obtain our own CE mark approval for the Urgent PC product.

We are 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 76% and 81%, respectively, of total net sales during fiscal 2005 and 2004. 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.

Even if our products receive 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 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

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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.

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

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

be expensive and time consuming to defend;

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

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

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

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

divert the attention of our management; or

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

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

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

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

We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent products or processes or otherwise gain access to our unpatented proprietary technology. We attempt to protect our trade secrets and other unpatented proprietary technology through the use of confidentiality 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 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.

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The I-Stop sling is manufactured by CL Medical in France. CL Medical could experience manufacturing and control problems, and we may not be able to scale-up manufacturing in a timely manner or manufacture sufficient quantities at a reasonable cost.

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 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. In fact, one of the suppliers of a component material of our Macroplastique product recently ceased production of this material. Although we have located an alternative supplier, and believe that alternative suppliers for our other materials exist, we cannot be sure that acceptable alternative arrangements could be made on a timely basis. 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. The European Union also imposes 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 expectations. In the United States, we intend to build our own sales and marketing organization to market our products directly and support our distributor organizations. We will incur significant additional expenses to establish this sales and marketing team. We likely will begin to incur some of these 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:

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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 2005, we had two customers that accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% 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 derive all of our net sales from operations in international markets. We expect non-United States sales to continue to represent a substantial portion of our revenues until our products obtain requisite FDA approvals and we achieve sufficient market acceptance from United States customers. 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;

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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 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.

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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.

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

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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 Sam B. Humphries, our President and Chief Executive Officer. Mr. Humphries continuation with us is integral to our future success, based on his significant expertise and knowledge of our business and products. We have no key person insurance with respect to Mr. Humphries, and any loss or interruption of his services could significantly reduce our ability to effectively manage our operations and implement our strategy. Also, we depend on the continued service of key managerial, scientific, sales and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. We compete for such personnel with other companies, academic institutions, government entities and other organizations. Any loss or interruption of the services of our other key personnel could also significantly reduce our ability to effectively manage our operations and meet our strategic objectives because we cannot assure you that we would be able to find an appropriate replacement should the need arise.

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

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

Our future liquidity and capital requirements will depend on numerous factors, including:

- the timing and cost associated with obtaining FDA approval of Macroplastique, the I-Stop sling and the Urgent PC nerve stimulation device;
- the timing and cost involved in manufacturing scale-up and in establishing 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.

To the extent that our existing capital is insufficient to meet our working capital needs and cover any losses, we will need to raise additional financing to achieve our business objectives. We currently have no committed sources of, or other arrangements with respect to, additional financing. 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 OTC Bulletin Board. Transactions on the OTC Bulletin Board may lack the volume, liquidity and orderliness necessary to maintain a liquid and active trading market. Accordingly, an investor should consider the potential lack of liquidity before investing in our common stock.

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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, the I-Stop sling and the Urgent PC nerve stimulation device;

market acceptance of our products;

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

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

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

developments in U.S. or international reimbursement systems;

changes in accounting standards, policies, guidance or interpretations;

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

general economic conditions.

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. In fact, we plan to file, at our expense, a registration statement under the Securities Act relating to the offer and sale from time to time into the public market by certain of our existing stockholders of 3,323,070 shares of our common stock (including shares underlying warrants owned by such stockholders). In addition, upon obtaining the effectiveness under the Securities Act of this registration statement, we expect to file, at our expense, an additional registration statement under the Securities Act covering the issuance of up to 806,218 shares of common stock that existing securityholders may acquire upon the exercise of outstanding warrants. Further, we have also registered 1,051,523 shares of common stock underlying options granted, and which may be granted, under our stock option plans. As of June 22, 2005, 928,259 outstanding options are immediately exercisable.

We will need to monitor and implement finance and accounting systems, procedures and controls as we grow our business and to satisfy new reporting requirements.

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 fiscal 2005 year-end closing process did not ensure that all significant elements of our consolidated financial statements were adequately reviewed. In our post-closing and audit processes, certain issues were discovered by us and our independent registered public accounting firm 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 for the year ended March 31, 2005 were completed, and they are properly accounted for in our consolidated 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.

Although the items described above were properly accounted for before completing our consolidated financial statements, 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 have discussed the material weakness described above with our audit committee. Our management is working with our audit committee to identify and implement corrective actions where required to improve the effectiveness of our internal controls, including the enhancement of our systems and procedures. Specifically, we are enhancing and formalizing our period-end closing processes to ensure that all significant elements of our consolidated financial statements are adequately reviewed.

During the fiscal 2004 year end closing process, we determined that our Dutch employee pension plan should have been reported as a defined benefit plan and discovered an error in how we recorded the effect of exchange rates on cash and cash equivalents in our statement of cash flows. As a result, we restated our consolidated financial statements as of and for the fiscal year ended March 31, 2003, and for the first three quarters in fiscal 2004. In connection with our fiscal 2004 audit, our then independent registered public accounting firm cited these restatements as reportable conditions. A reportable condition is a matter that in the independent auditors judgment could adversely affect our ability to process, summarize and report financial data consistent with the assertions of management in our

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financial statements. To remediate the conditions, our accounting personnel are more carefully reviewing our contracts and agreements and we have a new internal control procedure regarding how we record the effect of exchange rates on our statement of cash flows.

We cannot provide assurance that the measures we have taken to date or any future measures will adequately remediate the deficiencies or conditions discussed above. In addition, we cannot be certain that other reportable conditions or material weaknesses in our internal controls will not be discovered in the future. Any failure to remediate reportable conditions or material weaknesses or to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations, or result in material misstatements in our financial statements. Any such failure also could adversely affect the results of the periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that will be required when the SEC s rules under Section 404 of the Sarbanes-Oxley Act become applicable to us in April 2006.

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, 2007 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 since there is presently no precedent available by which to measure compliance adequacy. 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 exercise our option to acquire the assets of CystoMedix or any other company in the future, we may incur substantial additional costs to bring any acquired company s systems into compliance with Section 404.

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. Currently, we are generally not required to record compensation expense in connection with stock option grants to employees. Because we will be required to expense the fair value of employee stock option grants, it reduces the attractiveness of granting stock options because of the additional expense associated with these grants, which will negatively impact our results of operations. If the fair value method had been adopted, the net loss for fiscal 2005, and 2004 would have been $2,321,745, and $253,374 higher than reported and net loss per share would have been increased $0.50, and $0.06 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. Accordingly, after SFAS 123(R) becomes effective, our results of operations will be negatively impacted if we continue to use stock options as an employee recruitment and retention tool.

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

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of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

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

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

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

ITEM 2. DESCRIPTION OF PROPERTY

We own 9,774 square feet of office and warehouse space in Geleen, The Netherlands. In addition, we lease 13,705 square feet of office, warehouse, laboratory and production space through February 2006 in Minneapolis, Minnesota, which serves as our corporate office. We further lease 5,230 square feet of office and warehouse space through September 2011 (subject to our right to terminate early starting in 2006) in Reading, United Kingdom and 2,330 square feet of office, warehouse, laboratory and manufacturing space through June 2007 in Eindhoven, The Netherlands.

We believe our facilities are currently adequate to meet our needs. However, we may need additional office, production and warehouse space upon FDA approval of our products and subsequent increases in production, marketing and sales activities in the U.S.

ITEM 3. LEGAL PROCEEDINGS

We recently terminated the services of our former Vice President of Research and Development and Managing Director of our United Kingdom subsidiary. Although the individual has commenced no litigation against us, he has demanded up to 400,000 (or approximately $500,000) in severance compensation under Dutch law. We have rejected this claim and intend to defend against it if a formal suit commences.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We did not submit any matter to a vote of its 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.

The following table sets forth the high and low bid prices for our Common Stock, as reported by bigcharts.com for the OTC Bulletin Board system (market symbol UPST.OB; formerly UROP.OB) on a quarterly basis, from April 2004 through March 2005. Such quotations represent interdealer prices, without retail markup, mark down or commission, and do not necessarily represent actual transactions.

Fiscal Quarters	Low Bid	High Bid
First Quarter	$ 2.60	$ 5.25
Second Quarter	2.90	4.60
Third Quarter	4.10	6.30
Fourth Quarter	3.15	5.50

As of March 31, 2005, approximately 528 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, 2005.

	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	685,859	$ 3.14	16,900
Equity Compensation Plans Not Approved by Security Holders (1)	1,135,000	$ 4.46	45,431
Total	1,820,859	$ 3.96	62,331

(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. These stock options may be granted to our employees, directors, non-employees and consultants. We reserved a total of 449,998 shares of common stock under this plan, of which 45,431 remain available for future grant. In January 2005, pursuant to an employment agreement with Sam B. Humphries, our President and Chief Executive Officer, and an employment and consulting agreement with Daniel G. Holman, our Chairman and Chief Financial Officer, we granted them options to acquire 400,000 and 100,000 shares, respectively, of our common stock at an exercise price of $5.19 per share. Mr. Humphries options vest contingent upon his continued employment in one-quarter installments over a three-year period, beginning in January 2005. Mr. Holman s options vested 50% in January 2005 and will vest 25% in each of January 2006 and 2007. The options for both executives have a term of 10 years and will fully vest upon a change in control of us. 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 addition, we have

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granted an aggregate of 320,000 stock options to our various directors for their services, exercisable for five years from the date of grant at exercise prices ranging between $1.10 and $6.75.

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.

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, I-Stop and Urgent PC products.

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

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

Acquire or license complimentary products if appropriate opportunities arise.

In furtherance of our first key strategy above, we are concluding a multi-center human clinical trial using Macroplastique in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency. This is the weakening of the muscles that control the flow of urine from the bladder. We recently filed a pre-market approval (PMA) submission with the FDA describing Macroplastique use for this indication. For the I-Stop tape, we plan to submit to the FDA a 510(k) pre-market notification application in 2005. We are also responsible for obtaining and/or maintaining FDA and foreign regulatory approvals for the Urgent PC system. Although the Urgent PC device currently has U.S. pre-market clearance, we intend to file our own 510(k) pre-market notification application in 2005 for the version of the device we intend to sell. We will incur substantial expense in connection with these regulatory activities.

In the United States, we intend to build our own sales and marketing organization to market our products directly and support our distributor organizations. We will incur significant additional expenses to establish this sales and marketing team. We likely will begin to incur some of these expenses in advance of any anticipated regulatory approval, which we could not recoup if we do not receive such approval.

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.

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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 are estimated not to be 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, 2005 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.

Set forth below is management s discussion and analysis of the financial condition and results of operations for the fiscal years ended March 31, 2005 and 2004. See Note 7 to our Consolidated Financial Statements for business segment information.

Results of Operations

Net Sales. In fiscal 2005, net sales of all products were $6.7 million, representing a 16% increase when compared to net sales of $5.7 million for fiscal 2004. Excluding fluctuations in foreign currency exchange rates, we had a sales increase of approximately 8%. The net sales increase is partly contributed by price increases, but mainly attributable by increased unit sales. We believe the continued increase in net sales is related to the impact and execution of sales

plans designed to expand our global market share in the specialties of both urinary and fecal incontinence. The Macroplastique product line accounts for 76% and 81% of total net sales, respectively, during the periods presented. We also depend on key customers. During fiscal 2005, two customers accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% and 11% of our net sales.

Gross Profit. Gross profit was $4.9 million and $4.3 million for the fiscal years ended March 31, 2005 and 2004, respectively, or 74% and 75% of net sales. Gross profit as a percentage of net sales in any one specific period will continue to fluctuate, 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 gross margins on direct sales); and

currency fluctuations.

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Over the past several fiscal years, our gross margin has ranged from approximately 70-80% of net sales. This primarily relates to our Macroplastique products.

General and Administrative Expenses. General and administrative (G&A) expenses increased from $2.1 million during fiscal 2004 to $2.3 million during fiscal 2005. The G&A expense increase related to increases of $231,000 in personnel costs due to additional staff and increased salaries, a $217,000 increase in professional fees for accounting and legal services, an increase of $187,000 in bad debt expense, mainly to reserve for a receivable of one of our distributors, general price increases and fluctuations in foreign currency exchange rates. This increase was offset by decreased consulting expenses of $135,000 and decreased shareholders expenses of $349,000. The decrease in both the consulting fees and the shareholders expenses primarily relates to $473,000 of stock-based compensation expense we recognized in fiscal 2004.

Research and Development Expenses. Research and development (R&D) expenses increased 24% from $1.8 million during fiscal 2004 to $2.3 million during fiscal 2005. The increase in R&D expense is primarily due to quality and regulatory costs related to the development of our pre-market approval (PMA) submission for U.S. market clearance for Macroplastique in the treatment of adult female stress urinary incontinence.

Selling and Marketing Expenses. Selling and marketing (S&M) expenses increased 18% from $1.7 million during fiscal 2004 to $2.0 million during fiscal 2005. This increase resulted from a $210,000 increase in personnel costs, an additional $164,000 in costs relating to trade-shows, conventions and congresses, general price increases, and fluctuations in foreign currency exchange rates. The increase was offset by a decrease in promotional costs of $73,000. The increased personnel costs relate to the hiring of experienced sales personnel and increased salaries and bonuses.

Other Income (Expense). Other income (expense) includes interest income, interest expense, foreign currency exchange gains and losses, and other non-operating costs when incurred. Other income (expense) was $(12,000) and $60,000 for the fiscal years ended March 31, 2005 and 2004, respectively. 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 gains (losses) of $(16,000) and $46,000 for the periods presented. We cannot predict the impact of currency fluctuations on our future results.

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 45 days after the effective date of a new registration statement that we currently plan to file covering the shares underlying these warrants. In April 2005, we recognized a liability of $1.4 million associated with the grant of these new warrants. We will report in earnings any subsequent change in the fair value of this liability.

Income Tax Expense. Our Dutch subsidiaries recorded income tax expense of $92,000 and $229,000 for the periods presented, as they have fully utilized their net operating loss carryforwards. We cannot use our U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions. We expect continued profits for our Dutch subsidiaries and therefore continued income tax expenses. For fiscal 2005, the Dutch income tax rate was 29% for the first 22,689 (approximately $29,000) of profit and 34.5% thereafter.

Liquidity and Capital Resources

Cash Flows. As of March 31, 2005, our cash and cash equivalent balances totaled $1.5 million.

At March 31, 2005, we had working capital of approximately $2.4 million. During fiscal 2005, we used $1.3 million of cash in operating activities, compared to $600,000 of cash used in the prior fiscal year. The usage of cash was primarily attributable to the net loss incurred of $1.7 million. Accounts receivable, other current assets, accounts payable and accrued expenses fluctuated due to the timing of payments and fluctuations in foreign currency exchange rates. We recorded $473,000 of non-cash stock-based compensation expense during fiscal 2004.

Our financial condition and results of operations could be materially affected by fluctuations in foreign currency exchange rates and weak economic conditions in foreign markets where we sell and distribute our products. 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.

Sources of Liquidity. In March 2005, we entered into a business loan agreement with Venture Bank, pursuant to which we may borrow up to $500,000 on a revolving basis. All amounts which the bank advances to us are due in March 2006, unless the bank renews the agreement. Amounts advanced to us accrue interest at a variable rate of 1% in excess of the published prime rate in the Wall Street Journal, with a minimum rate of 6% per annum. We are obligated to pay interest monthly on the outstanding principal balance. Advances under this agreement are secured by substantially all our assets. At March 31, 2005 we had no outstanding balance under the agreement.

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 warrants are exercisable for five years at an exercise price of $4.75 per share.

Commitments and Contingencies. We believe that our current resources, funds generated from sale of our products outside the U.S. along with existing bank arrangements and the proceeds received from the recently completed private placement will be adequate to meet our cash flow needs, including regulatory activities associated with existing products, through fiscal 2006. Ultimately, we will need to achieve profitability and positive cash flows from operations to fund our operations and grow our business beyond fiscal 2006.

We expect to continue to incur significant costs for regulatory activities associated with obtaining regulatory approval in the United States for Macroplastique, the I-Stop sling and Urgent PC device. For fiscal 2006, we have budgeted approximately $3 million for our R&D expenses. We also expect that during fiscal 2006, our selling and marketing expenses will increase as we prepare for the initial U.S. marketing of our products. In addition, we currently expect general and administrative expenses in fiscal 2006 to increase as we 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. We paid CystoMedix an initial royalty payment of $225,000 and are paying an additional $250,000 in 12 monthly installments of $20,833. 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 option 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 option price will increase at a rate of 10% per year after April 2007. 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. 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. Depending on our available cash, we might need to raise additional equity or debt funds in order to consummate the CystoMedix acquisition, should we elect to do so.

We are obligated to pay royalties of 5% of net sales in the U.S. of Macroplastique products 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 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. This defined benefit plan is closed for new employees effective April 2005. As of that date, the Dutch subsidiary established a defined contribution plan. The Company s UK subsidiary defined benefit plan also was closed to further accrual for all employees effective December 31, 2004. In March 2005, the UK subsidiary established a defined contribution plan.

Under our agreement with CL Medical for the I-Stop product, we have agreed to purchase our entire requirement of product components from CL Medical. Contingent on U.S. FDA clearance of the product for U.S. sale, we also have specified minimum purchase requirements of $240,000 of units in the first year thereafter, increasing to approximately $1.9 million of units over a five year period, subject to periodic adjustment based on the value of the Euro.

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Repayments of our contractual obligations, consisting of royalties, notes payable and operating leases, are summarized below:

	Payments Due by Period			
	Total	Fiscal 2006	Fiscal 2007	Fiscal 2008 and Thereafter
Minimum royalty payments	$ 876,500	$ 558,167	$ 124,833	$ 193,500
Notes payable	505,871	44,606	44,606	416,659
Operating lease commitments	443,105	315,195	94,588	33,322
Total contractual obligations	$ 1,825,476	$ 917,968	$ 264,027	$ 643,481

Recent Accounting Pronouncements

In May 2005, the FASB issued FASB Statement No. 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) effected 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.

In November 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or 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 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.

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. We expect the provisions of SFAS 123(R) to result in a significant charge to compensation expense, as we currently do not recognize stock compensation expense in accordance with SFAS 123(R).

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 is effective for us in fiscal 2006. We do not expect adoption of FIN 47 to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued Staff Position FSP 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004.* The American Jobs Creation Act of 2004 introduces a special one-time dividends received deduction on the repatriation of certain foreign earnings to a U.S. taxpayer, provided certain criteria are met. FSP 109-2 provides accounting and disclosure guidance for the repatriation provision, and was effective immediately upon issuance. Adoption did not have an 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

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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

KPMG LLP (KPMG) previously served as our independent registered public accounting firm. On June 4, 2004, KPMG declined to stand for reelection and informed us that the client-auditor relationship between KPMG and us ceased upon completion of KPMG s audit of our consolidated financial statements as of and for the year ended March 31, 2004 and the issuance of KPMG s report thereon. In connection with the audits of the two fiscal years ended March 31, 2004, and the subsequent interim period through July 28, 2004 (the date that KPMG completed its audit), there were no disagreements with KPMG on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures, which disagreements if not resolved to KPMG s satisfaction would have caused KPMG to make reference in connection with its opinion to the subject matter of the disagreement.

KPMG cited two reportable conditions in its communications to our audit committee on July 29, 2004 related to the restatement of our consolidated financial statements as of and for the year ended March 31, 2003: (i) the correcting of an error in how we account for our Dutch pension plan and (ii) the correcting of an error in how we record the effect of exchange rates on cash and cash equivalents on our statement of cash flows.

The audit reports of KPMG on our consolidated financial statements as of and for the years ended March 31, 2004 and 2003 did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope or accounting principles; except that KPMG s report on our consolidated financial statements as of and for the years ended March 31, 2004 and 2003, contained a separate paragraph stating As discussed in note 2 to the consolidated financial statements, the Company has restated its consolidated financial statements for the year ended March 31, 2003.

A letter from KPMG was previously filed as an exhibit to our March 31, 2004 annual report in accordance with paragraph (a)(3) of item 304 of Regulation S-B.

On August 10, 2004, our audit committee engaged McGladrey & Pullen, LLP as our new independent registered public accounting firm. During fiscal 2003 and 2004, and during the subsequent interim period through August 10, 2004, we did not consult with McGladrey & Pullen, LLP regarding the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on our consolidated financial statements.

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. Except as described below, there have been no changes in our internal control over financial reporting during the fiscal quarter ended March 31, 2005, 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 that all significant elements of our consolidated financial statements were adequately reviewed. In our post-closing and audit processes, certain issues were discovered by us and our independent registered public accounting firm 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 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, 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

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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 have discussed the material weakness described above with our Audit Committee. Our management is working with our Audit committee to identify and implement corrective actions where required to improve the effectiveness of our internal controls, including the enhancement of our systems and procedures. Specifically, we are enhancing and formalizing our period-end closing processes to ensure that all significant elements of our consolidated financial statements are adequately reviewed.

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.

During the fiscal 2004 year end close process, we determined that the pension plan covering our Dutch employees had historically been reported as a defined contribution plan, but should have been reported as a defined benefit plan. We restated our March 31, 2003 consolidated balance sheet and the fiscal 2003 consolidated statement of operations for the impact of accounting for this pension plan as a defined benefit plan. In connection with preparing this restatement, we further discovered an error in how we recorded the effect of exchange rates on cash and cash equivalents on our statement of cash flows. We also restated our fiscal 2003 consolidated statement of cash flows for the impact of this accounting.

In July 2004, our previous independent registered public accounting firm at that time, cited these restatements of our consolidated financial statements as reportable conditions in its communication to our audit committee, and we agreed with this characterization. To remediate the situation, our accounting personnel more carefully review our contracts and agreements. In the first quarter of fiscal 2005, we also adopted a new internal control procedure regarding how we record the effect of exchange rates on our statement of cash flows.

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

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.

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ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits incorporated by reference.

Number	Description
2.1	First Amended Joint Plan of Reorganization (Modified) of the Company dated January 31, 1994 (Filed as Exhibit 8.1 to Form 10-SB)
3.1	Articles of Incorporation of Uroplasty, Inc. (Filed as Exhibit 2.1 to Form 10-SB)
3.2	Bylaws of Uroplasty, Inc. (Filed as Exhibit 2.2 to Form 10-SB)
4.1	Form of Stock Certificate of the Company representing shares of the Company s Common Stock (Filed as Exhibit 3.1 to Form 10-SB)
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 (Filed as Exhibit 6.1 to Form 10-SB)
10.2	Purchase and Sale Agreement dated December 1, 1995 by and among Bio-Vascular, Inc., Bioplasty, Inc., and Uroplasty, Inc. (Filed as Exhibit 6.2 to Form 10-SB)
10.3	License Agreement dated December 1, 1995 by and between Bio-Vascular, Inc. and Uroplasty, Inc. (Filed as Exhibit 6.3 to Form 10-SB)
10.4	Lease Agreement dated January 10, 1995 between Summer Business Center Partnership and Uroplasty, Inc. (Filed as Exhibit 6.4 to Form 10-SB)
10.5	Unsecured $640,000 Promissory Note dated March 30, 1994 by and between Bioplasty, Inc., Uroplasty, Inc. and Bioplasty Product Claimants Trust (Filed as Exhibit 6.5 to Form 10-SB)
10.6	Agreement and Satisfaction dated January 30, 1995 by and between Bioplasty Product Claimants Trust and Bioplasty, Inc. (Filed as Exhibit 6.6 to Form 10-SB)
10.7	Asset Sale and Satisfaction of Debt Agreement dated June 23, 1995 by and between Bioplasty, Inc. and Uroplasty, Inc. (Filed as Exhibit 6.7 to Form 10-SB)
10.8	Executory Contract Assumption Stipulation dated December 28, 1993 by and between Bioplasty, Inc., Uroplasty, Inc., and Collagen Corporation (Filed as Exhibit 6.8 to Form 10-SB)
10.9	Settlement and License Agreement dated July 23, 1992 by and between Collagen Corporation, Bioplasty, Inc., and Uroplasty, Inc. (Filed as Exhibit 6.9 to Form 10-SB)
10.10	Employment Agreement between Uroplasty, Inc. and Daniel G. Holman dated December 7, 1999. (Filed as Exhibit 10.10 to Form 10-KSB/03-31-2000.)
10.11	Employment Agreement between Uroplasty, Inc. and Christopher Harris dated December 7, 1999. (Filed as Exhibit 10.11 to Form 10-KSB/03-31-2000.)

10.12 Employment Agreement between Uroplasty, Inc. and Susan Holman dated December 7, 1999. (Filed as Exhibit 10.13 to Form 10-KSB/03-31-2000.)

10.13 Employment Agreement between Uroplasty, Inc. and Larry Heinemann dated December 7, 1999. (Filed as Exhibit 10.14 to Form 10-KSB/03-31-2000.)

10.14 Agreement, dated October 14, 1998, by and between Uroplasty, Inc. and Samir M. Henalla (pertaining to Macroplastique Implantation System). (Filed as Exhibit 10.15 to Form 10-KSB/A /03-31-2001)

10.15 Employment Agreement between Uroplasty, Inc. and Mr. Marc Herregraven dated November 15, 2002. (Filed as Exhibit 10.15 to Form 10-KSB/03-31-2003)

10.16 Consulting Agreement between Uroplasty, Inc. and Executive Advisory Group dated April 1, 2003. (Filed as Exhibit 10.16 to Form 10-KSB/03-31-2003)

10.17 Stock Option Agreement between Uroplasty, Inc. and Executive Advisory Group dated April 1, 2003. (Filed as Exhibit 10.17 to Form 10-KSB/03-31-2003)

10.18 Consulting Agreement between Uroplasty, Inc. and C.C.R.I Corporation dated April 1, 2003. (Filed as Exhibit 10.18 to Form 10-KSB/03-31-2003)

10.19 Manufacturing and Distribution Agreement with CL Medical SAS dated September 2, 2004 (Filed as Exhibit 10.19 to Form 10-QSB/09-30-2004)

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Number	Description
10.20	Employment Agreement with Sam B. Humphries dated January 1, 2005 (Filed as Exhibit 10.1 to Form 10-QSB/12-31-2004)
10.21	Employment and Consulting Agreement with Daniel G. Holman dated January 1, 2005 (Filed as Exhibit 10.2 to Form 10-QSB/12-31-2004)
10.22	Exclusive Manufacturing and Distribution Agreement with Cystomedix, Inc. dated April 18, 2005 (Filed as Exhibit 10.19 to Form 8-K/04-18-2005)
10.23	(Form of) Securities Purchase Agreement dated April 21, 2005 (Filed as Exhibit 10.20 to Form 8-K/04-26-2005)
10.24	(Form of) Warrant (Filed as Exhibit 10.21 to Form 8-K/04-26-2005)
10.25	(Form of) Registration Rights Agreement dated April 21, 2005 (Filed as Exhibit 10.22 to Form 8-K/04-26-2005)
16	Letter re Change in Certifying Accountant, dated July 29, 2004 (Filed as Exhibit 16 to Form 10-KSB/03-31-2004)

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

Number	Description
10.26	Business Loan Agreement and related Promissory Note dated March 24, 2005 with Venture Bank
13	Financial Statements
21	Subsidiaries of the Company
23.1	Consent of Independent Registered Public Accounting Firm McGladrey & Pullen, LLP
23.2	Consent of Independent Registered Public Accounting Firm KPMG LLP
31	Certifications by the CEO and CFO pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certifications by the CEO and CFO pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

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SIGNATURES

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

Dated: June 29, 2005

UROPLASTY, INC.

By /s/ Sam B. Humphries

Sam B. Humphries
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/ Sam B. Humphries	President, Chief Executive Officer and	June 29, 2005
Sam B. Humphries	Director (Principal Executive Officer)	
/s/ Daniel G. Holman	Chief Financial Officer and	June 29, 2005
Daniel G. Holman	Director (Principal Financial and Accounting Officer)	
/s/ Joel R. Pitlor	Director	June 29, 2005
Joel R. Pitlor		
/s/ R. Patrick Maxwell	Director	June 29, 2005
R. Patrick Maxwell		
/s/ Thomas E. Jamison	Director	June 29, 2005
Thomas E. Jamison		