UROPLASTY INC
Form 424B3
June 07, 2007

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PROSPECTUS SUPPLEMENT NO. 24 Filed pursuant to Rule 424(b)(3)
(To Prospectus dated May 1, 2006) Registration No. 333-133072

UROPLASTY, INC.
1,918,809 Shares of Common Stock
and
1,180,928 Shares of Common Stock
Issuable Upon Exercise of Warrants

This prospectus supplement relates to shares of our common stock that may be sold at various times by certain selling shareholders. You should read this prospectus supplement no. 24, the prior prospectus supplements and the prospectus dated May 1, 2006, which are to be delivered with this prospectus supplement. Our May 1, 2006 prospectus is a combined prospectus under Rule 429(a) of the Securities Act of 1933, as amended, with our prior prospectus dated July 29, 2005 and supplements thereto (See Registration No. 333-126737 filed with the Securities and Exchange Commission on July 20, 2005 and declared effective on July 29, 2005).

This prospectus supplement contains our Annual Report on Form 10-KSB for the fiscal year ended March 31, 2007. This report was filed with the Securities and Exchange Commission on June 6, 2007. The attached information supplements and supersedes, in part, the information contained in the prospectus.

Our common stock is traded on the American Stock Exchange under the symbol UPI. On June 6, 2007, the closing price of our common stock on the American Stock Exchange was $4.50 per share.

This investment is speculative and involves a high degree of risk. See Risk Factors on page 6 of the prospectus to read about factors you should consider before buying shares of the common stock.

Neither the SEC nor any state securities commission has approved or disapproved these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

Prospectus Supplement dated June 7, 2007

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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, 2007
Commission File No. 000-20989
UROPLASTY, INC.
(Name of Small Business Issuer in its Charter)

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

5420 Feltl Road
Minnetonka, Minnesota 55413-2820
(Address of principal executive offices)
(952) 426-6140
(Issuer s telephone number, including area code)

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

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 there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of Company s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. þ

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

Issuer s revenues for its most recent fiscal year: $8,311,001

The aggregate market value of the voting stock held by non-affiliates computed by reference to the price at which the stock was sold or the average bid and asked prices of such stock as of May 29, 2007 was $40,998,000.

The number of shares outstanding of the issuer s only class of common stock on May 29, 2007 was 13,160,700.

Documents Incorporated By Reference: Portions of our Proxy Statement for our 2007 Annual Meeting of Shareholders (the Proxy Statement), are incorporated by reference in Part III.

Transitional Small Business Disclosure Format: 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 products for the treatment of voiding dysfunctions. Our minimally invasive products treat urinary and fecal incontinence and overactive bladder symptoms. We believe that our company is uniquely positioned because we offer a broad and diverse set of products to address the various preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. We currently offer three medical devices for the treatment of incontinence and overactive bladder symptoms.

Our Strategy

Our goal is to gain market share in the voiding dysfunction market by expanding our portfolio of minimally invasive products for the treatment of voiding dysfunctions, with a particular focus on products and applications for outpatient and office-based procedures. We believe that, with a suite of innovative products, we can increasingly garner the attention of key physicians, our independent sales representatives and distributors to enhance market acceptance of our products. The key elements of our strategy are to:

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

Grow our U.S. sales and international distribution. We believe that in addition to international markets, the U.S. is a significant opportunity for future sales of our products. In order to grow our U.S. business, we have expanded our sales organization, consisting of direct field sales and independent sales representatives, marketing organization and reimbursement department to market our products directly to our customers. We anticipate further increasing, as needed, our sales and marketing organization in the United States to support our sales growth. In addition, we intend to expand our European presence by creating new distribution partnerships.

Educate physicians and patients about the benefits of our Urgent® PC neuromodulation system. We believe education of physicians and patients regarding the benefits of our Urgent PC is critical to the successful adoption

of this product. To this end, we have initiated a clinical trial, which is a U.S. multi-center randomized prospective study comparing the Urgent PC device to the most commonly prescribed pharmaceutical treatment

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for OAB symptoms. We believe the results of this and other studies, if successful, will allow us to expand our marketing and sales efforts. These sales and marketing efforts may include physician training and education programs which will emphasize the clinical efficacy and ease of use of our Urgent PC product as well as patient-oriented marketing materials for physicians to use to inform patients of the availability and potential benefits of our Urgent PC product.

Provide patient-driven alternatives. Patients often weigh the quality of life benefits of electing to undergo a surgical procedure against the invasiveness of the procedure. We intend to continue to expand our marketing efforts to build patient awareness of these treatment alternatives and encourage patients to see physicians. We believe this will help physicians build their practices and simultaneously increase sales of our products.

Develop, license or acquire products. We believe that our broad and diverse product offering is an important competitive advantage because it allows us to address the various preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. An important part of our growth strategy is to broaden our product line further to meet customer needs by developing new products internally, licensing or acquiring new products through acquisitions.

Our Products

Macroplastique® Implants is a minimally invasive, implantable soft tissue bulking agent for the treatment of 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 has been sold for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from the U.S. Food and Drug Administration (FDA) pre-market approval for the use of Macroplastique to treat female stress urinary incontinence. We began marketing this product in the United States in early 2007. We cannot assure that we can market Macroplastique profitably in the U.S. 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 Urgent® PC neuromodulation system is a minimally invasive device designed for office-based treatment of overactive bladder symptoms of urinary urge incontinence, urinary urgency and urinary frequency. This product uses percutaneous tibial nerve stimulation to deliver an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. We received regulatory approvals for the sale of Urgent PC in the United States and Canada in October 2005 and in Europe in November 2005. Subsequently, we launched the product for sale in those markets. We launched our second generation Urgent PC product in 2006.

I-Stop™ is a minimally invasive biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. Our I-Stop sling can correct stress urinary incontinence by providing tension-free, hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine. We stopped selling this product in the U.S. in March 2007, but continue selling it in the United Kingdom.

Sales, Marketing and Distribution

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

Outside of the United States, we sell our products primarily through a direct sales organization in the United Kingdom and primarily through distributors in other markets. Each of our distributors has a territory-specific distribution agreement, including requirements that they may not sell products that directly compete with ours. Collectively, our distributors accounted for approximately 52% and 65% of total net sales for fiscal 2007 and 2006, respectively.

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

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Voiding Dysfunctions

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

The Problem of Urinary Incontinence

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

Causes of Urinary Incontinence

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

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

Types of Urinary Incontinence

There are four types of urinary incontinence:

Stress Urinary Incontinence - Stress urinary incontinence (SUI), refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from ordinary physical activities, such as coughing, sneezing, laughing, straining or lifting. For the majority of women with SUI (9 million of the 11 million in the U.S.), their incontinence is caused by urethral hypermobility. Urethral hypermobility abnormal movement of the bladder neck and urethra occurs when the anatomic supports for the bladder neck and urethra have weakened. This anatomical change is often the result of childbirth. Stress urinary incontinence can also be caused by intrinsic sphincter deficiency, or the inability of the sphincter muscle to function properly. Intrinsic sphincter deficiency can be due to congenital sphincter weakness or can result from deterioration of the urethral muscular wall due to changes of aging or damage following trauma, spinal cord lesion or radiation therapy. The National Association for Continence (NAFC) estimates up to 15% of female stress urinary incontinence is a result of intrinsic sphincter deficiency (ISD). For many women, their SUI is a combination of urethral hypermobility and ISD.

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

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

Mixed Incontinence - Mixed incontinence is the combination of both urge and stress incontinence (and, in some cases, overflow). Clinicians estimate that 30% of women suffering from stress urinary incontinence also exhibit symptoms of urge incontinence. Since prostate enlargement often obstructs the urethra, older men often have urge incontinence coupled with overflow incontinence.

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Management and Curative Treatment of Urinary Incontinence

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

Management of Urinary Incontinence

Absorbent Products. Absorbent products are the most common form of management for urinary incontinence because men and women can use them without consulting a physician. The cost of adult diapers and pads can be substantial and create a continuous financial burden for patients. Additionally, this management technique may require frequent changing of diapers and pads to control patient embarrassment due to odor or soiling.

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

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

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

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

Curative Treatment of Urinary Incontinence

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

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

Synthetic bulking agents include solid silicone elastomers, pyrolytic carbon-coated beads, and calcium hydroxylapetite.

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. Numerous publications cite sling procedure efficacy greater than 85%.

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

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Uroplasty Solutions for Urinary Incontinence

We believe that we are uniquely positioned with differentiable, minimally invasive products to address both causes of SUI.

Macroplastique® Implants

Macroplastique® Implants is a minimally invasive, 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 treatment by Macroplastique, which is approved for such use outside of the United States.

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

We have sold Macroplastique for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from the FDA pre-market approval for the use of Macroplastique to treat female SUI. We began marketing this product in the United States in early 2007. We cannot assure that we can market Macroplastique profitably in the U.S.

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

I-Stop Sling

The I-Stop™ tape, a biocompatible, tension-free, mid-urethral sling, is FDA-approved and CE-marked for the treatment of female urinary incontinence due to urethral hypermobility. If the urethra is no longer appropriately supported by the surrounding tissues and ligaments, the urethra may move too easily and may no longer properly close. A sling provides a hammock-type support for the urethra to prevent its downward movement, and associated leakage of urine, during periods of increased abdominal pressure.

I-Stop, the only synthetic, mid-urethral sling made of monofilament knitted polypropylene, has closed loop edges, which we believe make it non-damaging to surrounding tissue without the need for a delivery sheath. We also believe that the I-Stop design provides greater strength and controlled flexibility, and improved resistance to fragmentation, stretching and deformity during the outpatient implant procedure, than competitive sling devices

We sell the I-Stop only in the United Kingdom under an exclusive distribution agreement ending in 2010 with the manufacturer, CL Medical SAS of Lyon, France. Under the agreement, we have minimum purchase requirements each year. If we fail to reach the minimum purchase requirements, CL Medical has the right to terminate our exclusive distribution rights. We discontinued selling the I-Stop in the United States in March 2007.

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.

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Treatment of Overactive Bladder Symptoms

Drug Therapy. The most common treatment for OAB is drug therapy using an anticholinergic agent. However, for some individuals, the drugs are ineffective or the side effects so bothersome that the patient discontinues the medications. Common side effects include dry mouth, constipation, headache, fatigue, urinary retention, nausea, dizziness, blurred vision, anxiety and the possibility of unwanted interactions with other drugs.

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

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

The sacral nerve stimulator uses a small device, a neurostimulator, to send mild electrical pulses to the sacral nerve. The sacral nerve is located in the lower back, just above the tailbone. The surgically implanted neurostimulator contains a battery and electronics to create the electrical pulses and is connected to a neurostimulation lead (an insulated wire) containing electrodes through which stimulation is delivered to the nerve. The device is most frequently placed under the skin of the buttock, with the lead under the skin near the spine. Patients need to have subsequent surgeries performed to replace the stimulator battery and, if needed, to replace a malfunctioning unit or correct for a dislodged lead.

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. We believe 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

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 just above the ankle, the product delivers an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function.

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

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix, Inc., an Andover, Minnesota medical device company, for the exclusive rights to manufacture and market the Urgent PC neuromodulation system for the U.S., Canada and all countries recognizing the CE mark. Although the Urgent PC as marketed by CystoMedix was CE marked and 510(k) cleared, following minor revisions to the product, we secured 510(k) clearance for the device in October 2005 and CE mark in November 2005. Subsequently, we launched the product for sale in those markets. In 2006, we received additional regulatory clearance and launched our second generation Urgent PC product.

In April 2007 we acquired from CystoMedix certain intellectual property assets related to the Urgent PC product and terminated the April 2005 exclusive manufacturing and distribution agreement.

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The Problem of Fecal Incontinence

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

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

Treatment of Fecal Incontinence

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

Uroplasty Solutions for Fecal Incontinence

We have two minimally invasive products to address fecal incontinence. Our PTQ Implants, implanted circumferentially into the submucosa of the anal canal, offer a minimally invasive treatment for patients with fecal incontinence. This soft-textured, permanent implant creates a bulking and supportive effect for the internal anal sphincter. This product is CE marked and currently sold outside the U.S. in various international markets. We also secured the CE mark for the application of percutaneous tibial nerve stimulation for the treatment of fecal incontinence. Our Urgent PC is sold for the treatment of fecal incontinence in countries recognizing the CE mark.

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 distribution agreement.

Manufacturing and Suppliers

We have two manufacturing facilities: A facility in Eindhoven, The Netherlands, and a facility in Minnetonka, Minnesota. We are in the process of transitioning our production from our Eindhoven facility, which we plan to close, to our facility in Minnesota. We expect to complete this manufacturing transition in late 2007, pending FDA qualification of our facility in Minnesota. If we do not receive timely FDA qualification of our facility in Minnesota, we will have to delay our plans to exit our Eindhoven facility.

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

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

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

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We source our I-Stop sling from CL Medical, who designs and manufactures the product.
We currently subcontract the manufacturing of the Urgent PC and its related components.

Competition

The market for voiding dysfunction products is intensely competitive. Competitors offer management and curative treatments, including commercialized tissue bulking agents, urethral sling products and neurostimulation devices. Indirect and future competitors include drug companies and firms developing new or improved treatment methods. We believe the principal decision factors among treatment methods include physician and patient acceptance of the treatment method and cost, availability of third-party reimbursement, marketing and sales coverage and the existence of meaningful patent protection. In addition to addressing the decision factors, our ability to effectively compete in this market will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors affecting our success include our product development and innovation capabilities, clinical study results, ability to obtain required regulatory approvals, ability to protect our proprietary technology, manufacturing and marketing capabilities and ability to attract and retain skilled employees.

Soft-tissue injectable bulking agents competing directly with Macroplastique®, both outside and in the U.S. include FDA-approved Contigen® bulking agents manufactured by C.R. Bard, Inc.; Zuidex® and Deflux® (Deflux FDA approved for vesico-ureteric reflux (VUR) use only) manufactured by Q-Med AB; Durasphere® (FDA-approved for female SUI) manufactured by Carbon Medical Technologies; and Coaptite® manufactured by BioForm, Inc. for Boston Scientific. In contrast to the competitors products currently approved for sale, Macroplastique, is a synthetic material that will not degrade, resorb or migrate, has no special preparation or storage requirements and does not require the patient to have a skin test prior to the procedure. The silicone-elastomer material has been studied for over 50 years in medical use for such urological applications as artificial urinary sphincters, penile implants, stents and catheters. Our patented Macroplastique® Implantation System offers a unique, non-endoscopic, minimally invasive out-patient procedure that can be performed in the physician s office.

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

The Urgent®PC neurostimulation device is an alternative to the more invasive Medtronic InterStim® device. The Medtronic unit, which stimulates the sacral nerve, requires surgical implantation in the upper buttocks or abdomen, with recurring surgical intervention to replace the stimulator battery and, if needed, to replace a malfunctioning unit or correct for a dislodged lead. In contrast, the Urgent PC device allows minimally invasive stimulation of the sacral nerve plexus in an office-based setting without surgical intervention. Neotonus markets a non-surgical device to deliver extracorporeal magnetic neuromodulation. In addition, Boston Scientific s Bion® Microstimulator, a device implanted with a needle-like instrument to stimulate the pudendal nerve, is CE mark approved for the treatment of urinary urge incontinence and is undergoing clinical studies in the U.S.

Many medications treat symptoms of overactive bladder, some by preventing unwanted bladder contractions, others by tightening the bladder or urethra muscles and some by relaxing bladder muscles. Sometimes, these drugs have unwanted side effects such as dry mouth, vision problems or constipation. Among these medications are Detrol® (Pfizer Inc.), Ditropan® (Alza Corporation), Enablex® (Novartis), Vesicare® (GlaxoSmithKline) and Flomax® (Abbott Laboratories).

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

Government Regulation

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

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United States

The FDA under the Food, Drug and Cosmetic Act regulates our products in the Unites States as medical devices. Noncompliance with applicable requirements can result in, among other things:

fines, injunctions, and civil penalties;

recall or seizure of products;

operating restrictions, or total or partial suspension of production;

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

withdrawal of existing approvals; and

criminal prosecution.

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

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

After a device receives 510(k) clearance for a specific intended use, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that would constitute a major change to the intended use of the device will require a new 510(k) pre-market notification submission or, depending upon the changes, could require pre-market approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision. If the FDA disagrees with a manufacturer s determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) clearance 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 FDA approves the IDE application, human clinical trials may begin at a specific number of investigational sites with a maximum number of patients. The results of clinical testing may not be sufficient to obtain approval of the product.

After the FDA determines that a pre-market approval application is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted pre-market approval application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or

clarification of information already provided. Also during this review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulations. New pre-market approval applications or supplemental pre-market approval applications are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the pre-market approval process. Pre-market approval supplements often require submission of the same type of information as a pre-market approval, except that the supplement is limited to information needed to support any device changes not covered by the original pre-market approval application, and may not require as extensive clinical data as the original submission or the convening of an advisory panel.

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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 serious injury if it were to recur;

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

notices of correction or removal, and recall regulations.

FDA Oversight of Manufacturing Operations. The Food, Drug and Cosmetics Act requires that medical devices be designed and manufactured in accordance with the FDA s current Quality System Regulations, which require, among other things, that we:

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

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

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

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

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

Third-Party Reimbursement

In both U.S. markets and markets outside the U.S., sales of our products will depend in part on the availability of reimbursement from third-party payors. Outside of the United States, government managed health care systems and private insurance control reimbursement for devices and procedures. Reimbursement systems in international markets vary significantly by country. In the European Union, reimbursement decision-making is neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government. Reimbursement for Macroplastique and other tissue bulking products has been successful in multiple international markets where hospitals and physicians have been able to get budgets approved by fund-holder trusts or global hospital budgets.

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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.

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

We believe that for our U.S. market there are appropriate reimbursement codes describing endoscopic use of Macroplastique to treat female SUI. However, we will still need to foster coverage policies and payer acceptance of Macroplastique. There is no guarantee that Macroplastique will be covered or reimbursed at the levels expected by us, if at all.

Patents, Trademarks and Licenses

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

We hold multiple patents covering our Macroplastique materials, processes and applications. As of the date of this report, we have four issued U.S. patents and 20 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. In addition, in April 2007 we acquired one granted and several pending patents when we purchased from CystoMedix certain intellectual property assets related to the Urgent PC. We are awaiting prosecution of the patent protection applications we filed in 2006 for the Urgent PC. We cannot assure that we will obtain this or any other patent protection. There can also be no assurance any of our issued patents are of sufficient scope or strength to provide meaningful protection of our products nor can there be any assurance that 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.

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

We also seek to protect our trade secrets by requiring key employees, consultants, and other parties to sign confidentiality and noncompetition agreements, and by limiting access by outside parties to confidential information. There can be no assurance, however, these measures will prevent the unauthorized disclosure or use of this information or that others will not be able to independently develop this information.

We have registered Macroplastique®, Uroplasty®, VOX®, PTQ® and Bioplastique® as trademarks with the U.S. Patent and Trademark Office. In addition, Macroplastique is registered throughout the European Union. CystoMedix has U.S. registration of the Urgent® PC trademark and, as part of our exclusive manufacturing and distribution agreement, licensed the mark to us. We acquired the trademark rights in April 2007 when we purchased from CystoMedix certain intellectual property assets. 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.

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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, enhance existing, and evaluate potential new incontinence products. Additionally, this program incurs costs for regulatory submissions, regulatory compliance and clinical research. Clinical research includes studies for new products, new applications or indications for existing products, post-approval marketing, and reimbursement approval by third party payors. Our expenditures for research and development totaled $2.3 and $3.3 million for fiscal 2007 and 2006, 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. There can be no assurance, however, our existing insurance coverage limits are adequate to protect us from any liabilities we might incur, including if liability claims exceed our 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 2007 and 2006 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During fiscal 2007, two customers each accounted for approximately 10% of our net sales. During fiscal 2006, the same two customers accounted for approximately 14% and 11% of our net sales.

Employees

As of March 31, 2007, we had 51 employees, of which 48 were full-time and 3 were part-time. No employee has a collective bargaining agreement with us. We believe we maintain good relations with our employees.

Incorporation and Current Subsidiaries

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

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

Uroplasty BV	Incorporated in The Netherlands, distributes the Urgent PC and wound care products, and is the manufacturer of Macroplastique, Bioplastique, VOX Implants, PTQ Implants and all of their accessories. Products are sold primarily through distributors. We plan to discontinue our manufacturing operations in The Netherlands and transition the production to our facility in Minnesota in calendar 2007.
Uroplasty LTD	Incorporated in the United Kingdom and acts as the sole distributor of Urgent PC, Macroplastique, Bioplastique, PTQ Implants, all of their accessories, and wound care products in the United Kingdom and Ireland. Also distributes the I-Stop in the United Kingdom. Products are sold primarily through a direct sales organization.

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RISK FACTORS

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

We continue to incur losses and may never reach profitability

We have incurred net losses in each of the last five fiscal years. As of March 31, 2007, we had an accumulated deficit of approximately $16 million primarily as a result of costs relating to the development, including seeking regulatory approvals, and commercialization of our products. We expect our operating expenses relating to sales and marketing activities, product development and clinical trials, including for FDA-mandated post-market clinical study for our Macroplastique product will continue to increase during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability achieve widespread market acceptance for our products and successfully expand our business in the U.S., which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

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

Our future liquidity and capital requirements will depend on numerous factors including: the timing and cost involved in manufacturing scale-up and in expanding our sales, marketing and distribution capabilities in the United States markets; the cost and effectiveness of our marketing and sales efforts with respect to our existing products in international markets; the effect of competing technologies and market and regulatory developments; and the cost involved in protecting our proprietary rights. Because we have yet to achieve profitability and generate positive cash flows, we will need to raise additional financing to support our operations and planned growth activities beyond fiscal 2008. Any equity financing could substantially dilute your equity interests in our company and any debt financing could impose significant financial and operational restrictions on us. There can be no guarantee that we will be successful, as we currently have no committed sources of, or other arrangements with respect to, additional equity or debt financing. We therefore cannot assure you that we will obtain additional financing on acceptable terms, or at all.

If we are not able to attract, retain and motivate our sales force and expand our distribution channels, our sales and revenues will suffer.

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

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

We are dependent on sales of our products that contain our Macroplastique bulking agent. Our Macroplastique product line accounted for 51% and 67%, respectively, of total net sales during fiscal 2007 and 2006. 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.

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

Our failure to achieve sufficient market acceptance of our products in the U.S., particularly for the Urgent PC, will 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. Furthermore, if our products do not achieve increasing market acceptance in the U.S. and internationally, our revenues will decline or we may be unable to increase our revenues and be profitable.

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 regulatory approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot assure that any of our products will be approved or continue to be approved for sale. Any failure to obtain or retain regulatory approvals or clearances could prevent us from successfully marketing our products, which could adversely affect our business and results of operations. Our failure to comply with applicable regulatory requirements could result in governmental agencies:

imposing fines and penalties on us;

preventing us from manufacturing or selling our products;

bringing civil or criminal charges against us;

delaying the introduction of our new products into the market;

enforcing operating restrictions;

recalling or seizing our products; or

withdrawing or denying approvals or clearances for our products.

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.

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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;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party s intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management; or
- result in our customers or potential customers deferring or limiting their purchases or use of the affected products until resolution of the litigation.

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

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

Our success depends in part on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patents and patent applications if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. In addition, patent protection in foreign countries may be different from patent protection under U.S. laws and may not be favorable to us. As a result, we may not be able to compete effectively. We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent products or processes or otherwise gain access to our unpatented proprietary technology. We attempt to protect our trade secrets and other unpatented proprietary technology through the use of confidentiality and noncompetition agreements with our current key employees and with other parties to whom we have divulged trade secrets. However, these agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event competitors discovery

or independently develop similar proprietary information.

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

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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.

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

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

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

If we are not able to maintain sufficient quality controls, regulatory approvals by the European Union, the FDA or other relevant authorities of our products 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 extensive testing, control, documentation and other quality assurance requirements. Canada and the European Union also impose requirements on quality systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Further, our suppliers are also subject to these regulatory requirements. Failure by any of our suppliers or us to comply with these requirements could prevent us from obtaining or retaining approval for and marketing of our products. We cannot assure you that our suppliers or our manufacturing facilities will comply with applicable regulatory requirements on a timely basis or at all.

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

If we are not able to acquire or license other products, our business and future growth prospects could suffer. As part of our growth strategy, we intend to acquire or license additional products and product candidates for development and commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right products.

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

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

- we may be unable to integrate the acquired business 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.

We had two customers, each accounting for approximately 10% of our net sales in fiscal 2007. During fiscal 2006, the same two customers accounted for approximately 14% and 11% of our net sales. As a result, we face the risk that one or more of our key customers may decrease business or terminate relationships with us. If we are unable to replace any decrease in business from these customers, it 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 semi-liquid silicone gel in breast implants, resulting in product liability litigation and leading to the bankruptcy of several companies, including our former parent, Bioplasty, Inc. We use only medical grade solid silicone material in our tissue bulking products and not semi-liquid silicone gel, as was used in breast implants. Negative publicity regarding the use of silicone materials in our products or in other medical devices could have a significant adverse affect on the overall acceptance of our products. We cannot assure you that the use of solid silicone in medical devices implanted in the human body by us and others will not result in negative publicity.

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

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

In addition, many of the countries in which we sell our products are, to some degree, subject to political, economic and/or social instability. Our international sales operations expose us and our representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

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