UROPLASTY INC
Form 10-K
July 23, 2013

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Fiscal Year Ended March 31, 2013

Commission File No. 001-32632

UROPLASTY, INC.
(Exact name of registrant as specified in its Charter)

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

5420 Feltl Road
Minnetonka, Minnesota 55343
(Address of principal executive offices)

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

Securities registered under Section 12(b) of the Exchange Act:

Title of class	Name of Exchange on which registered
Common Stock, $.01 par value	NASDAQ

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES o NO x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act.
YES o NO x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
YES x NO o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large Accelerated Filer ¨ Accelerated Filer x Non-Accelerated Filer ¨ Smaller Reporting Company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES o NO x

The aggregate market value of the voting stock and nonvoting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked prices of such common equity, as of September 30, 2012 was $67,481,196.

As of June 28, 2013, the registrant had 20,934,245 shares of common stock outstanding.

Documents Incorporated By Reference: Portions of our Proxy Statement for our 2011 Annual Meeting of Shareholders (the "Proxy Statement"), are incorporated by reference in Part III.

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FORWARD LOOKING STATEMENTS

This Form 10-K contains "forward-looking statements" relating to projections, plans, objectives, estimates, and other statements of future performance. These forward-looking statements are subject to known and unknown risks and uncertainties relating to our future performance that may cause our actual results, performance, achievements, or industry results, to differ materially from those expressed or implied in any such forward-looking statements. Our business operates in highly competitive markets and our operating results and the achievement of the forward-looking statements may be impacted by changes in general economic conditions, competition, reimbursement levels, customer and market preferences, government regulation, tax regulation, foreign exchange rate fluctuations, the degree of market acceptance of products, the uncertainties of potential litigation, and other matters detailed in the "Risk Factors" contained in Item IA of this report.

We do not undertake nor assume any obligation to update any forward-looking statements that we may make from time to time.

PART I

Item 1. Business

Overview

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. You can access, free of charge, our filings with the Securities and Exchange Commission, including our annual report on Form 10-K, our quarterly reports on Form 10-Q, current reports on Form 8-K and any other amendments to those reports, at our website www.uroplasty.com, or at the Commission's website at www.sec.gov.

Our primary focus is on two products: the Urgent PC® Neuromodulation System, which we believe is the only FDA-cleared, minimally-invasive, neuromodulation system that delivers percutaneous tibial nerve stimulation (PTNS) for office-based treatment of overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence; and Macroplastique® Implants, an injectable, urethral bulking agent for the treatment of adult female stress urinary incontinence primarily due to intrinsic sphincter deficiency (ISD). Outside of the U.S., our Urgent PC System is also approved for treatment of fecal incontinence, and Macroplastique is also approved for treatment of male stress incontinence, fecal incontinence, vocal cord rehabilitation and vesicoureteral reflux.

Our primary focus is on growth in the U.S. market, which we entered in 2005 with our Urgent PC System. Prior to that time, essentially all of our business involved the sale of Macroplastique and other products outside of the U.S. We believe the U.S. market presents a significant opportunity for growth in sales of our products.

The Urgent PC Neuromodulation System uses percutaneous stimulation to deliver to the tibial nerve electrical pulses that travel to the sacral nerve plexus, a control center for bladder function. We have received regulatory clearances for sale of the Urgent PC System in the United States, Canada and Europe. We launched sales of our second generation Urgent PC System in late 2006. We have intellectual property rights relating to key aspects of our neuromodulation therapy.

We have sold Macroplastique for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from the FDA pre-market approval for the use of Macroplastique to treat adult female stress urinary incontinence. We began marketing Macroplastique in the United States in 2007.

We believe physicians prefer our products because they offer effective therapies for patients that can be administered in office or outpatient surgical-based settings and, to the extent reimbursement is available, provide the physicians a profitable revenue stream. We believe patients prefer our products because they are minimally invasive treatment alternatives that do not have the side effects associated with pharmaceutical treatment options nor the morbidity associated with surgery.

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Developments

Our sales have been significantly influenced by the availability of third-party reimbursement for PTNS treatments. Sales of our Urgent PC System in the U.S. grew rapidly during fiscal 2007 and 2008 with rapid market acceptance of PTNS treatments that were reimbursed under a Category 1 Current Procedure Technology (CPT®) code. Sales declined from the first quarter of fiscal 2009 through the third quarter of fiscal 2011, because of lower or unavailable reimbursement when the American Medical Association (AMA) advised providers that reimbursement for PTNS treatments should requested under an unlisted CPT code.

We responded by sponsoring several clinical studies over the following two years that were published in U.S. peer-reviewed journals. With favorable results from these studies, we applied for, and effective January 2011 the AMA granted, a new Category 1 CPT code for PTNS treatments. As a result, we expanded our U.S. field sales and support organization from 15 employed sales representatives and six independent manufacturer's representatives on April 1, 2010 to 39 employed sales representatives on March 31, 2013, and sales of our Urgent PC System began to increase.

We have since focused our efforts on expanding reimbursement coverage with Medicare carriers and private payers by instituting a comprehensive program to educate their medical directors regarding the clinical effectiveness, cost effectiveness and patient benefits of PTNS treatments using our Urgent PC System. After a positive coverage decision by Wisconsin Physician Services effective June 1, 2013, regional Medicare carriers representing 48 states and the District of Columbia, with approximately 46 million covered lives, provide coverage for PTNS treatments. In addition, we estimate that private payers insuring approximately 97 million lives provide coverage for PTNS treatments. At June 1, 2013, one regional Medicare carrier representing 2 states, with approximately 3 million covered lives, continued to decline reimbursement coverage for PTNS treatments.

With the availability of a CPT Category 1 code and expanded reimbursement coverage from third-party payers, as well as an expanded sales organization, sales of our Urgent PC System in the U.S. increased 84% in the year ended March 31, 2012 over the year ended March 31, 2011, and continued this positive trend with 35% growth to $10.5 million in the year ended March 31, 2013. Overall revenue growth slowed somewhat in the year ended 2013, as sales in the U.S. of our more mature Macroplastique product and sales outside of the U.S. declined.

We expect to continue to emphasize sales of our Urgent PC System in the United States, and have retained new management to restructure our sales organization. The intent is to increase our focus on training physicians on the continued use and benefits of a treatment regime using the Urgent PC System for overactive bladder. As part of this process, we intend to test the use of clinical support specialists in some of our markets. We also have earmarked additional marketing dollars for the coming fiscal year to better introduce our products to both those members of the public most likely to require treatment with the device, and to key opinion leaders in the urology markets. We do not expect to see significant growth in our U.S. Macroplastique business, because we believe it is a small, mature market that is more competitively penetrated than the market for OAB treatment using PTNS.

Products and Markets

Both of our products are targeted at the market for treatment of voiding dysfunctions and address overlapping submarkets. Voiding dysfunctions affect urinary or bowel control and can result in uncontrolled bladder sensations (overactive bladder) or unwanted leakage (urinary or bowel/fecal incontinence).

We believe that over the next several years a number of key demographic and technological factors will accelerate growth in the market for medical devices to treat OAB and other urinary and bowel voiding dysfunctions. These factors include the following:

- Technology advances and patient awareness. Patients often weigh the clinical benefits, adverse side effects and the level of invasiveness of the procedures, along with other factors, in choosing a treatment alternative. In recent years, with the publicity associated with new technology and minimally invasive treatment alternatives, we believe the number of patients visiting physicians to seek treatment for voiding dysfunctions has increased. As a result, we believe more patients will choose to avoid drug therapy or, because of adverse side effects, choose to discontinue drug therapy for other alternatives which more simply and effectively manage their disorder.

- Emphasis on quality of life. Patients have placed an increased emphasis on quality of life issues and maintaining active lifestyles. Their desire to improve their quality of life is usually an important factor in selecting a treatment for their disorder. We believe patients seeking treatment are increasingly considering alternatives designed to balance the therapeutic effect with any associated side effects. As a result, we believe patients will increasingly choose minimally invasive surgical treatments or other effective treatments such as neuromodulation.

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- Aging population. The number of individuals developing voiding dysfunctions will increase as the population ages and as life expectancies rise.

Overactive Bladder

Symptoms. For individuals with overactive bladder symptoms, the nervous system control for bladder filling and urinary voiding is incompetent. For OAB patients, signals to indicate a full bladder are sent early and frequently, triggers to allow the bladder to relax for filling are ineffective, and nervous controls of the urethral sphincter to keep the bladder closed until an appropriate time are inadequate. An individual with OAB may exhibit one or all of the symptoms that characterize overactive bladder: urinary urgency, urinary frequency and urge incontinence. Urgency is the strong, compelling need to urinate and frequency is a repetitive need to void. For most individuals, normal urinary voiding is about eight times per day while individuals with OAB may seek to void over 20 times per day and more than two times during the night. Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate that typically results in an accident before the individual can reach a restroom.

Treatment of Symptoms. When patients seek treatment for OAB, physicians normally start with conservative therapies such as biofeedback and behavioral modification. When, as is often the case, these therapies are not entirely successful, the next treatment of choice is drug therapy. If, as is the case with a majority of the patients, the drug therapy is ineffective or cannot be tolerated by the patient, the physicians suggest other treatments. For those patients, we believe the minimally invasive Urgent PC treatments offer an alternative to the more invasive treatments such as surgery or implantation of a sacral nerve stimulation device.

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

Drug Therapy. The most common treatment for OAB is drug therapy using an anticholinergic agent. However, for many patients, drugs are ineffective or the side effects are so bothersome that they discontinue the medications. Common side effects include dry mouth, dry eyes, constipation, cognitive changes and blurred vision.

Neuromodulation. Normal urinary control is dependent upon properly functioning neural pathways and coordination among the central and peripheral nervous systems, the nerve pathways, the bladder and the sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to OAB symptoms. Therapy using neuromodulation incorporates electrical stimulation to target specific neural tissue and “jam” the pathways transmitting unwanted signals. To alter bladder function, stimulation must be delivered to the sacral nerve plexus, which innervates the bladder and pelvic floor. Neuromodulation to treat OAB may be performed by a surgically implanted sacral nerve stimulation device or performed in a physician’s office by the non-surgical PTNS procedure delivered by the Urgent PC.

- Surgical. Direct sacral nerve stimulation devices consist of a surgically implanted lead near the spine and an implanted stimulator in the buttocks to deliver mild electrical pulses to the sacral nerve plexus. We believe most office-based physicians will first recommend drug therapy or PTNS treatments to patients before the more invasive, surgically implanted procedure. We believe patients may be more inclined to elect a less invasive treatment option for urinary symptoms instead of an invasive surgery that could be associated with complications.

- Minimally Invasive. PTNS delivers stimulation to the sacral nerve plexus by temporarily applying electrical pulses to the posterior tibial nerve, accessed through a non-surgical, percutaneous approach on the lower leg. Neuromodulation using PTNS has a therapeutic effect documented in published clinical studies. PTNS has a low risk of complications and is typically performed in a physician’s office, quite often by a qualified health care provider other than the physician, because it is a non-surgical treatment.

The Uroplasty Solution: The Urgent PC Neuromodulation System. The Urgent PC Neuromodulation System is a minimally invasive nerve stimulation device designed for office-based treatment of OAB and the associated symptoms of urge incontinence, urinary urgency and urinary frequency. Using a small-gauge needle electrode inserted above the ankle, the Urgent PC System delivers electrical impulses to the tibial nerve that travel to the sacral nerve plexus, a control center for pelvic floor and bladder function.

We believe that the Urgent PC System is the only FDA-cleared PTNS device in the United States market for treatment of OAB. Components of the Urgent PC Neuromodulation System include a hair-width needle electrode, a lead set and an external, handheld, battery-powered stimulator. For each 30-minute office-based therapy session, the physician or other qualified health care provider inserts the needle electrode above the ankle and connects the electrode to the stimulator. Typically, a patient undergoes a course of 12 consecutive weekly treatments, and, subsequently, a personal treatment plan of single treatments at lesser frequency to sustain the therapeutic effect.

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In late 2005, we received regulatory clearances for sale of the Urgent PC System in the United States, Canada and Europe. Subsequently, we launched the System for sale in those markets. We launched our second generation Urgent PC System in late 2006.

Urinary Incontinence.

Symptoms and Prevalence. Urinary incontinence is defined as the involuntary loss of urine, and is a very common health problem, especially among women. In 2007, the US Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases reported that, depending on the definition of urinary incontinence used, 5% to 50% of the adult U.S. population suffers from some form of urinary incontinence. The prevalence of urinary incontinence increases with advancing age, and the prevalence of U.S. population with urinary incontinence is expected to grow over the next decades as the U.S. population ages. Urinary incontinence often results in social isolation, depression, and poor self-rated health and quality of life, and is a significant medical condition with considerable public health impact.

Causes of Urinary Incontinence. The mechanisms of urinary continence are complex 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, especially with increased intra-abdominal pressure. Urination occurs when the sphincter relaxes as the bladder contracts, allowing urine to flow through the urethra. Incontinence may result when any part of the urinary tract fails to function as intended. Incontinence may be caused by damage during childbirth, pelvic trauma, spinal cord injuries, neurological diseases (e.g., multiple sclerosis and poliomyelitis), birth defects (e.g., spina bifida) and degenerative changes associated with aging.

Types of Urinary Incontinence. There are four types of urinary incontinence:

- Stress Urinary Incontinence — Stress urinary incontinence (SUI), refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from ordinary physical activities, such as coughing, sneezing, laughing, straining or lifting. SUI, the most common form of urinary incontinence among women, is estimated to affect almost 30 million women over the age of 18 in the U.S. (Hampel et al., 1997 and 2000 U.S. census data). SUI is caused by urethral hypermobility and/or intrinsic sphincter deficiency (ISD). Urethral hypermobility – abnormal movement of the bladder neck and urethra – occurs when the anatomic supports for the bladder neck and urethra have weakened. This anatomical change is often the result of pregnancy or childbirth. SUI can also be caused by ISD, or the inability of the sphincter valve or muscle to function properly. ISD can be due to congenital sphincter weakness or can result from deterioration of the urethral muscular wall due to aging or damage following trauma, spinal cord lesion or radiation therapy.

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

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

- Mixed Incontinence — Mixed incontinence is the combination of both urge and stress incontinence (and, in some cases, overflow). Since prostate enlargement often obstructs the urethra, older men often have urge incontinence coupled with overflow incontinence.

Treatments. There are two general approaches to dealing with urinary incontinence. One approach is to manage symptoms, such as through absorbent products, catheters, behavior modification and drug therapy. The other approach is to undergo curative treatments in an attempt to restore continence, such as injection of urethral bulking agents or surgery, or a combination of the two. We believe that patients prefer less invasive treatments that provide the most benefit and have little or no side effects.

Injectable Bulking Agents. Urethral bulking agents (UBAs) are injected into the area around the urethra, to augment the surrounding tissue for increased capacity to control the release of urine for patients with SUI. Hence, these materials are often called “bulking agents” or “injectables” and are an attractive alternative to surgery because they are considerably less invasive, offer a quick recovery, and do not require the use of an operating room for placement; UBAs can be implanted in an office or out-patient facility. Additionally, the use of a UBA does not preclude the subsequent use of more invasive treatments if required. Furthermore, UBAs may be used to resolve lingering symptoms for patients who have undergone certain more invasive treatments, such as mid-urethral slings, which failed to completely resolve the stress urinary incontinence conditions.

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Surgery. In women, SUI may be corrected through surgery with a mid-urethral sling which provides a hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine.

The Uroplasty Solution: Macroplastique Implants. Macroplastique is used to treat adult female stress urinary incontinence due to ISD. It is designed to restore the patient's urinary continence immediately following treatment. Macroplastique is a soft-textured, permanent implant injected, under endoscopic visualization, around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone elastomer) implants suspended in a biocompatible excretable carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site.

We have sold Macroplastique for several urological indications in over 40 countries outside the United States since 1991. In October 2006, we received FDA pre-market approval for the use of Macroplastique to treat adult female SUI due to ISD. We began marketing Macroplastique in the United States in early 2007.

Other Uroplasty Products and Applications

Macroplastique® for Vesicoureteral Reflux. Outside the U.S., we market the Macroplastique Implant products for treatment of vesicoureteral reflux: the abnormal backflow of urine from the bladder into the ureters or kidneys that is most prevalent in infants and children where the ureters did not fully develop. In this application a bolus of the elastomer implant is injected around the orifice or valve where the ureter enters the bladder.

PTQ® Implants. We also market our silicone elastomer implants under the name PTQ® Implants outside of the U.S. as a minimally invasive product to address fecal incontinence (sometimes referred to as bowel incontinence). Our PTQ Implants offer minimally-invasive, soft-textured permanent implant for treatment of fecal incontinence. PTQ is implanted circumferentially into the submucosa of the anal canal, creating a "bulking" and supportive effect around the anal sphincter. PTQ is CE marked and currently sold outside the United States in various international markets.

Urgent PC for Fecal Incontinence. The Urgent PC Neuromodulation System is CE marked and sold outside of the United States for the treatment of fecal incontinence. We also intend to explore the commercialization of Urgent PC for this application in the U.S. and started on a multiyear pilot clinical trial in fiscal 2013 as a prelude to a full clinical study for FDA clearance.

VOX® Implants. In addition to urological applications, we market our silicone elastomer bulking material outside the United States to help improve speech and swallowing function in patients with unilateral vocal cord paralysis. The implants are sold for vocal cord rehabilitation applications under the trade name VOX® Implants.

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

Uroplasty Strategy

Our goal is to become the leading provider of minimally invasive, office and outpatient surgical-based solutions to treat and improve the quality of life for patients suffering the physical and emotional stress resulting from voiding dysfunction problems. We believe that with our Urgent PC Neuromodulation System and Macroplastique products we can increasingly garner the attention of key physicians and distributors to grow our revenue. The key elements of our strategy are to:

- Increase market coverage in the United States. We believe the United States presents a significant opportunity for growth in sales of our products. In order to grow our business in the United States, we anticipate further increasing our sales and marketing organization, as needed, to support our sales growth.

- Educate physicians and third-party insurance carriers about the benefits of Urgent PC. We believe education of physicians and third-party insurance carriers regarding the benefits of the Urgent PC System is critical to the successful adoption of this System, and to reimbursement for treatments by third-party carriers. To this end, we have conducted clinical studies which we believe will help us with our sales and marketing efforts.

- Build patient awareness of office and outpatient surgical-based solutions. Patients often weigh the quality of life benefits of electing to undergo a surgical procedure against the invasiveness of the procedure. We intend to continue to expand our marketing efforts to build patient awareness of the treatment alternatives and encourage patients to see physicians. These marketing efforts may include patient-oriented marketing materials for physicians to use to inform patients of the availability and potential benefits of our products. Increasing patient awareness of our treatment alternatives will help physicians build their practices and simultaneously increase sales of our products.

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- Initially focus on office and outpatient surgical-based solutions for physicians. We believe our company is uniquely positioned to provide a broad product offering of office and outpatient surgical-based solutions for physicians. By expanding our United States presence, we intend to develop long-standing relationships with leading physicians treating voiding dysfunctions. 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.

- Obtain FDA clearance to expand use of our Urgent PC System for other indications. Our Urgent PC Neuromodulation System is CE marked and sold outside of the United States for the treatment of fecal incontinence. We intend to explore the commercialization in the U.S of the Urgent PC System for the treatment of fecal incontinence. To commercialize the product in the U.S. for the treatment of fecal incontinence, we will need to conduct clinical trials for FDA clearance and for seeking reimbursement coverage from third-party payers. We started on a multiyear pilot clinical trial in fiscal 2013, planned to be followed by a pivotal clinical study needed for FDA clearance.

- Develop complementary products for long-term treatment. In fiscal 2013 we started on product design and development work, based on a patent we hold, for a minimally-invasive implantable tibial nerve stimulator for treatment of OAB. Our initial plans are to seek regulatory approval and CE mark to commercialize the product in Europe, with subsequent plans to seek regulatory approval to commercialize a redesigned product in the U.S.

- Develop, license or acquire new products. We believe that our office and outpatient surgical-based solutions are an important competitive advantage because they allow us to address the preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. An important part of our long term growth strategy is to broaden our product lines further to meet customer needs by developing, licensing and acquiring new products.

Sales, Distribution and Marketing

We are focusing our sales and marketing efforts primarily on urologists, urogynecologists and gynecologists with significant office-based and outpatient surgery-based patient volume.

To support our business in the United States, we have a sales organization, consisting primarily of 39 direct field sales representatives, a marketing organization to market our products directly to our customers and a reimbursement department. We anticipate further increasing our sales and marketing organization in the United States, as needed, to support our sales growth.

Outside of the United States, we sell our products primarily through a direct sales organization in the United Kingdom and The Netherlands, and in all other markets primarily through distributors. Each of our distributors has a territory-specific distribution agreement, including requirements indicating they may not sell products that compete directly with ours. Collectively, distributors accounted for approximately 14%, 17% and 25% of our total net sales for fiscal 2013, 2012 and 2011, respectively.

We use clinical studies and worldwide 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 and presentations at professional society meetings by clinical researchers add to the scientific community awareness of our products, including patient indications, treatment technique and expected outcomes. We provide a range of activities designed to support physicians in their clinical research.

Third-Party Reimbursement

In the United States as well as in foreign countries, sales of our products depend in significant part on the availability of reimbursement from third-party payers. In the United States, third-party payers consist of government programs such as Medicare, private health insurance plans, managed care organizations and other similar programs. For any product, three factors are critical to reimbursement:

·coding, which ensures uniform descriptions of procedures, diagnoses and medical products;

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

· payment processes and amounts.

We believe the availability of a Category 1 CPT code for PTNS treatments has encouraged, and will continue to encourage, broader use of and reimbursement for our Urgent PC System in the U.S. However, each governmental and private payer makes its own coverage decision.

With respect to Medicare reimbursement, each regional Medicare carrier is entitled to make a separate decision to provide coverage if at all, and the number of PTNS treatments covered. After a positive coverage decision by Wisconsin Physician Services effective June 1, 2013, regional Medicare carriers representing 48 states and the District of Columbia, with approximately 46 million covered lives, provide coverage for PTNS treatments. In addition, we estimate that private payers insuring approximately 97 million lives provide coverage for PTNS treatments. At June 1, 2013, one regional Medicare carrier representing 2 states, with approximately 3 million covered lives, continued to decline reimbursement coverage for PTNS treatments. Further the amount reimbursed and number of treatments that may be covered can vary from region to region and we continue to work with the various carriers to educate them in the positive results we have achieved with longer term clinical studies.

The Centers for Medicare and Medicaid Services has announced consolidation of some of the regional Medicare claims administrators. When this consolidation occurs, there is no guarantee that Medicare beneficiaries in a region with reimbursement coverage will continue to be reimbursed when consolidated into a regional Medicare carrier with a negative reimbursement policy, or, if reimbursed, the coverage would remain unchanged. We continue to work to clinically prove the benefits of longer term treatment using PTNS and to educate regional carriers about those benefits.

Outside of the U.S., Urgent PC treatments are reimbursed under an available reimbursement code in the Netherlands. In other countries in Europe there are no specific reimbursement codes for Urgent PC treatments and generally reimbursement is from fund-holder trusts or global hospital budgets.

We believe there are appropriate CPT codes available to describe the use of Macroplastique to treat adult female SUI due to ISD in the United States. Outside of the United States, government managed health care systems and private insurance control reimbursement for devices and procedures. Reimbursement systems in international markets vary significantly by country. In the European Union, reimbursement decision-making is neither regulated nor integrated at the European Union level. Each country has its own system, often closely protected by its corresponding national government. Reimbursement for Macroplastique has been successful in multiple international markets where hospitals and physicians have budgets approved by fund-holder trusts or global hospital budgets.

Manufacturing and Suppliers

We subcontract the manufacturing of the Urgent PC System and its related components, and have a U.S. FDA-registered manufacturing facility in Minnetonka, Minnesota, where we manufacture all of our tissue bulking products. Our facility uses dedicated heating, cooling, ventilation and high efficiency particulate air filtration systems to provide cleanroom and other controlled working environments. Our trained technicians perform all critical manufacturing processes in qualified environments according to validated written procedures. We use qualified vendors to sterilize our products using validated methods.

Our manufacturing facility and systems are periodically audited by regulatory agencies and other authorities to ensure compliance with ISO 13485 (medical device quality management systems), applicable European and Canadian medical device requirements, as well as FDA's Quality Systems Regulations. We also are subject to additional state,

local, and federal government regulations applicable to the manufacture of our products. While we believe we are compliant with all applicable regulations, we cannot guarantee that we will pass each regulatory audit.

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

Competition

The market for voiding dysfunction products is intensely competitive. Competitors offer management and curative treatments, pharmaceutical products such as anticholinergic drugs, injectable drugs, implantable including neuromodulation devices, urethral injectables and urethral sling products. We believe the principal decision factors among treatment methods include severity of patient symptoms and procedure risk, physician and patient acceptance of the treatment method, cost, availability of third-party reimbursement, and marketing and sales coverage. In addition to adequately addressing the decision factors, our ability to compete in this market will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors affecting our success include our product development and innovation capabilities, clinical study results, ability to obtain required regulatory approvals, ability to protect our proprietary technology, manufacturing and marketing capabilities and ability to attract and retain skilled employees.

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PTNS. We believe the Urgent PC Neuromodulation System offers a minimally invasive, office-based treatment alternative in the continuum of care for OAB patients. Conservative therapies such as dietary restrictions, pelvic floor exercises, bladder retraining, biofeedback, and anticholinergic drugs usually precede Urgent PC treatments. Anticholinergic medications that could be seen as competing with PTNS include Detrol® and Toviaz® (both by Pfizer Inc.); Ditropan® (Johnson and Johnson); Enablex® (Novartis); Sanctura® (Allergan) and Vesicare® (GlaxoSmithKline). These medications treat symptoms of overactive bladder, some by preventing unwanted bladder contractions and others by tightening the bladder or urethra muscles or by relaxing bladder muscles. We believe our Urgent PC System normally is prescribed after these drugs are used but discontinued because they were ineffective or had unwanted side effects. In the case of anticholinergic medications, the side effects often include dry eyes, dry mouth, constipation, cognitive changes and blurred vision.

Allergan, Inc. recently began to commercialize Botulinum toxin A (Botox®) for OAB treatments, and this treatment could be seen as direct competitor for Urgent PC following unsuccessful drug therapy. In this procedure, Botox is injected in and around the urethra, often with dozens of individual injection sites, to numb and mask the symptoms of urgency and frequency. Nevertheless, although we believe that marketing campaigns by Allergan will increase awareness of OAB, we also believe that the side effects of Botox injections for this application, which can include urine retention and urinary tract infection, will lead many patients to choose our less invasive solution.

The Medtronic InterStim neuromodulation device, which stimulates the sacral nerve, requires surgical implantation of a lead near the patient's spine in addition to a battery powered stimulator in the buttocks. In contrast, the Urgent PC Neuromodulation System allows minimally invasive stimulation of the sacral nerve plexus in an office-based setting without any surgical intervention. Other companies may also enter the U.S. market with neuromodulation or other products for the treatment of OAB.

Bulking. Injectable urethral bulking agents for SUI competing directly with Macroplastique in the United States include: Durasphere® manufactured by Carbon Medical Technologies and distributed by Coloplast; and Coaptite® manufactured by BioForm, Inc. and distributed by Boston Scientific. We believe Macroplastique competes favorably against these products because it will not degrade, resorb or migrate, has no special preparation or storage requirements, and is safe and effective for treating adult female stress urinary incontinence.

Outside of the United States, Deflux® (manufactured by Q-Med AB, Sweden and distributed by Salix Pharmaceuticals) and Bulkamid® (manufactured by Contura, Denmark and distributed by Johnson and Johnson) compete with Macroplastique for vesicoureteral reflux and SUI, respectively.

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

Government Regulation

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

United States

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

· fines, injunctions, and civil penalties;

· recall or seizure of products;

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- operating restrictions, or total or partial suspension of production;

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

- withdrawal of existing approvals; and

- criminal prosecution.

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

In October 2005, our initial version of the Urgent PC System received 510(k) clearance for sale within the United States. In July 2006, our second generation Urgent PC System received 510(k) clearance for sale within the United States.

In October 2006, we received FDA pre-market approval for the use of Macroplastique to treat female stress urinary incontinence in the United States. As part of the FDA-approval process, we are conducting a customary post-market study.

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

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

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

- medical device reporting regulations, which require that manufacturers report to 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; and

- notices of correction or removal, and recall regulations.

The FDC Act requires that medical devices be manufactured in accordance with FDA's current Quality System Regulations, which require, among other things, that we:

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

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

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

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

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

European Union and Other Regions

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

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

We received the CE mark approval for Macroplastique in 1996 for the treatment of male and female stress uri