



t r a n s i t i o n s

U R O L O G I X

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clinical

After a six-year, \$19 million investment in research, development, and clinical trials, Urologix received FDA clearance to commercially market the Targis™ System in the United States during fiscal 1998. Targis therapy is used to treat benign prostatic hyperplasia (BPH) – or enlarged prostate – an age-related condition affecting six million American men over the age of 50 and another 17 million men worldwide.



commercial

"We are beginning to witness a profound demographic shift – and the attendant prevalence of BPH – as Baby Boomers approach age 50 in increasing numbers. The Targis System enables our medical practices to satisfy intended clinical outcomes for BPH therapy while addressing growing consumer demand for minimally invasive alternatives to surgery." ~ *Stryker Warren, Jr., President and CEO, Urology Healthcare Group, Inc., Nashville, Tenn.*

LETTER TO SHAREHOLDERS

TO OUR SHAREHOLDERS Fiscal 1998 was marked by several important achievements. The year began with FDA approval of the Targis™ System for commercial marketing in the United States. In the second quarter, we strengthened our balance sheet with the completion of a secondary stock offering that raised more than \$30.0 million. In May, we prominently displayed the Targis System for the first time following U.S. approval at the annual meeting of the American Urological Association (AUA). This key industry meeting, attended by 10,000 urologists, drew a high level of attention and interest for the Targis System.

During the year, we achieved \$3 million in U.S. sales after actively marketing the Targis System domestically for just seven months. By year end, the number of men treated worldwide with our proprietary technology exceeded 2,000. Our clinical studies, which now include four-year data, demonstrate consistently good outcomes and the Targis System's durability as a safe and effective treatment for benign prostatic hyperplasia (BPH). In fact, in July, on the strength of our clinical data, the FDA approved an expanded claim of Targis treatment for obstructive BPH. Targis therapy is now indicated for both symptomatic and obstructive BPH with the same safe, effective and durable treatment protocol.

1998: THE YEAR IN REVIEW For the fiscal year ended June 30, 1998, revenues increased to \$11.2 million from \$5.5 million in 1997. Net loss for fiscal 1998 was \$15.0 million or \$1.44 per share, compared with a net loss of \$8.2 million, or \$0.90 per share a year ago. Higher operating expenses were a significant factor in the loss in fiscal 1998, and are the result of the Targis System's U.S. launch costs and building the necessary marketing infrastructure.

Targis therapy requires physicians to adopt an expanded treatment armamentarium for BPH, which includes not only drugs and surgery, but also a new technology. This is a complex issue, which we are addressing with a multi-faceted strategy built upon a stronghold of support for our technology's superiority among leading clinicians. From this foundation, we are opening and expanding channels of reimbursement; providing physician education to ensure continued good outcomes; tracking treatment outcomes to support the durability of Targis therapy; and working with physicians to develop patients' interest, knowledge and demand. Our focused consultative sales force is essential, too, underscoring both our commitment to the market while enhancing our presence in it.

MARKET DEVELOPMENT INITIATIVES PRODUCE KEY RESULTS Our market development initiatives produced significant results in 1998 and are paving the way for continued growth in the coming year. To date, more than 30 Targis control units are in operation in academic and urology centers nationwide, including over half of the top 20 U.S. urology centers as ranked in the July 27, 1998 issue of *U.S. News & World Report*. This achievement reflects increasing acceptance among opinion leaders and helps to validate the Targis System's clinical and economic advantages.

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More than 300 physicians have completed our Quality Outcomes Training program. This hands-on training ensures that the superior clinical results and durability achieved during clinical trials are continued in commercial settings. It also serves to expand our base of support within the broader urology community.

Targis therapy is generating a positive reimbursement record. Medicare carriers in 49 states have issued favorable reimbursement decisions for hospital-based Targis treatment. Private payers are routinely reimbursing for the treatment. An important priority for 1999 is to gain office-based reimbursement, which will allow the Targis System to be utilized in the manner for which it was ultimately designed: as a highly effective, low-cost, anesthesia-free, outpatient treatment for BPH.

We have begun clinical trials to validate a shorter therapy protocol. Reducing procedure time without compromising safety, efficacy or durability adds a measure of convenience not feasible with drugs or surgery — and will help to further differentiate Targis therapy as a preferred treatment for BPH.

We are beginning to see changes in physicians' practice patterns. Once clinics attain more than 90 days of experience with the Targis System, their procedure rates increase. In markets where we have public awareness programs in place to drive patient demand, utilization is significantly greater. Utilization is a key to our future, generating a recurring revenue stream from sales of disposable, single-use Targis procedure kits.

The long-term efficacy of Targis treatment continues to be validated by independent physician investigators, who publish their findings in peer-reviewed journals. During 1998, four favorable papers about the Targis technology and its excellent outcomes were published in the prestigious *World Journal of Urology*, *Journal of Urology*, and *UROLOGY*. Several more papers about the Targis System have been submitted to these journals, and at least three have been accepted for publication.

We continue to invest wisely in research and development to build and sustain our technology leadership position. We currently hold 16 U.S. patents, have applied for an additional 17 in the United States, and have licensed 9 others worldwide.

1999 STRATEGIES TARGET RAPID EXPANSION OF U.S. BUSINESS In fiscal 1999, we expect to expand our U.S. business through ongoing deployment of our marketing resources. We have implemented a two-tier sales force, which teams a senior sales person with a clinical specialist. This strategy separates the focus of the control unit sale — which benefits from a highly skilled consultative sales professional — from the after-sale component that targets increased utilization through on-going support and service at the clinic level.

We have also forged a new marketing alliance with Boston Scientific Corporation in the United States, which we believe will allow us to penetrate the market more quickly. Boston Scientific's Microvasive Urology sales force is one of the largest and most respected sales teams in the urology business, affording us immediate presence and credibility. While our sales organization has been effective in reaching and gaining acceptance among key opinion leaders, the Boston Scientific team complements and expands our efforts in the wider urology community.

While we anticipate replicating key components of our U.S. strategy in Europe and Japan, longer-than-anticipated selling cycles outside the United States have resulted in higher-than-expected distributors' inventories. As a result, we expect overseas revenues to slow in 1999.

We are resolved to build on the momentum of our early market successes in the United States. We believe that Targis treatment is a clinically superior alternative to existing BPH therapies, and the right technology for the current health care environment. With a solid long-term strategy to address the challenges of our marketplace, and the organizational infrastructure now in place to support it, we are prepared to make the final transition from clinical to commercial operations.

Finally, on behalf of the Board of Directors, employees and fellow shareholders, I would like to thank Jack Meyer for his many contributions to Urologix. Jack, who successfully led Urologix from a small development team to a publicly-held, commercial medical device company, stepped down as president and CEO on October 5. He will continue to contribute as a director. The search for a new president and CEO is proceeding, and several highly qualified candidates have been identified.

Looking ahead, we see opportunity, remain committed to improving our position, and are confident of our strategies. We appreciate your continued support, and look forward to reporting our progress to you.

Sincerely,

A handwritten signature in black ink that reads "Mitchell Dann". The signature is written in a cursive, slightly slanted style.

MITCHELL DANN, CHAIRMAN OF THE BOARD

November 6, 1998



tradition

Medical practice is clearly moving toward noninvasive treatments – like the Targis System – that use technology to achieve excellent clinical outcomes at reduced costs. With its high efficacy and proven durability, lower cost per treatment, minimal patient discomfort and lack of side effects, Targis treatment is an ideal fit with current managed care initiatives, and may well redefine the standard of care for BPH.

A man with grey hair, wearing a white lab coat over teal scrubs, stands in a clinical setting. He has his arms crossed and is looking directly at the camera. The lab coat has a name tag that reads "M.P. O'Leary, M.D." and "Analogist". In the background, there are wooden cabinets with various medical supplies, including boxes of "BARR" sterile items. A large surgical light fixture is visible in the upper right corner. A blue draped surface, likely a patient bed or table, is in the foreground. A white dashed arrow points from the left towards the word "future".

future

"Targis has shown real promise in achieving good, sustained results. The technology's key advantages are that it is minimally invasive and truly anesthesia-free. The procedure can be performed in the physician's office, which improves access and facilitates care and recovery – it's win-win for both clinicians and patients." ~ *Michael P. O'Leary, M.D., M.P.H., Associate Professor of Surgery, Harvard Medical School, Brigham and Women's Hospital, Boston, Mass.*

ONE-HALF OF ALL MEN OVER THE AGE OF 50 This represents the vast market potential for Urologix's proprietary Targis™ therapy — a huge,untapped opportunity that comprised 23 million men and \$8 billion in health care expenditures last year. It is a market driven by an aging population that is global and projected to double by the year 2020.

The issue at hand is the treatment of benign prostatic hyperplasia (BPH). Commonly known as enlarged prostate, BPH is an age-related condition for which the Targis System was specifically developed. The prostate is a walnut-sized gland surrounding the male urethra, located just below the bladder and adjacent to the rectum. As a man reaches middle age,cells within the prostate grow at an increased rate,enlarging the prostate and constricting the flow of urine through the urethra.

Although BPH is noncancerous and generally non-life-threatening,it can cause serious,irreversible bladder or kidney damage if left untreated. It also compromises the quality of life for those who suffer with it. Symptoms include frequent urination both day and night;a sudden urge to urinate;difficulty in starting and stopping urine flow;a weak flow of urine;and the nagging sensation that the bladder is not completely empty. It leaves many men sleepless,frustrated,and reluctant to participate in any activity that takes them too far from a rest room. BPH causes many formerly active men to become reclusive.

Currently, it is estimated that only 30 percent of patients with moderate to severe BPH symptoms seek treatment. While due in part to lack of information about the disease,the limitations of existing therapies lead the vast majority to opt for no treatment at all — a practice known as “watchful waiting.” But as symptoms inevitably worsen, watchful waiting becomes impractical.

TARGIS SYSTEM: SEIZING OPPORTUNITY WITH A BETTER OPTION Conventional medical treatments for BPH — drugs or surgery — can be risky, expensive or both. At first glance, drug therapy is more attractive because it is noninvasive. In fact,85 percent of patients who seek treatment for BPH opt for drug therapy as their first choice. But it has drawbacks. The drugs must be taken daily for life. Many men are not satisfied with the modest relief of their bothersome symptoms. Cost can be as much as \$12,000 to \$17,000 over a lifetime, depending upon the age that therapy begins. Side effects are common, ranging from dizziness to impotence. At least 30 percent of men discontinue the regimen within the first year.

Urologists often prefer surgery to drugs for some patients. A procedure known as transurethral resection of the prostate (TURP) is considered the gold standard for treating BPH. Success rates are high with a low incidence of re-operation. But

The Targis System affords BPH patients a new, better alternative to drugs or surgery. Targis therapy is a nonsurgical, anesthesia-free, catheter-based treatment. It employs a proprietary, targeted microwave energy to destroy only the diseased prostatic tissue with no damage to adjacent tissues or structures.

surgery burdens increasingly limited health system resources. Costing about \$5,000 to \$8,000 per case, TURP requires a highly skilled surgeon, anesthesia, a two-to-three day hospital stay, and a one-to-four week recovery period at home. The procedure also carries a risk of complications, including infection, bleeding, incontinence, impotence and retrograde ejaculation.

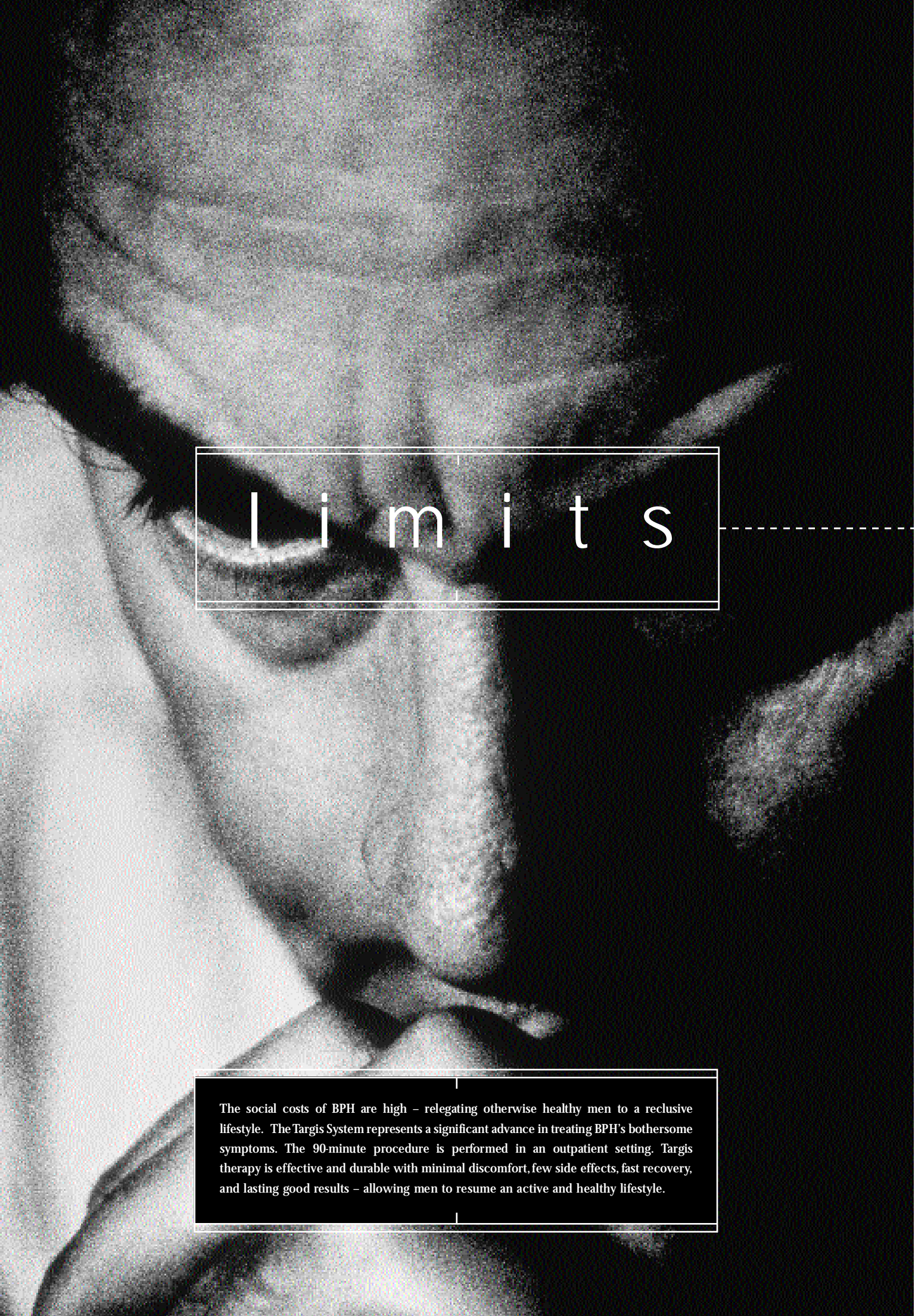
The Targis System affords BPH patients a new, better alternative to drugs or surgery. Targis treatment is a nonsurgical, anesthesia-free, catheter-based therapy that can be performed in a physician's office. It employs a proprietary method of targeting the delivery of microwave energy to destroy the diseased prostatic tissue with no damage to adjacent tissues or structures. Patients experience minimal discomfort in the 90-minute procedure. Clinical data have demonstrated Targis therapy to be a safe and tolerable treatment with fast recovery times and few side effects. The efficacy of Targis therapy far surpasses that of drugs and approaches that of TURP. The cost is one-third to one-half of conventional interventions.

LEVERAGING TECHNOLOGY IN A CHANGING ERA OF MEDICINE The economic impact of BPH in the United States is \$3 billion annually. In this era of managed health care, where quality is measured in terms of results and costs, Targis has clear advantages for patients, physicians and payers. As with other new treatment modalities, education and experience are key to acceptance, and Urologix has developed a comprehensive strategy to demonstrate the Targis System's myriad benefits to the marketplace.

Reimbursement is a central issue, and significant progress has been made to establish a positive payment record in the United States. A CPT procedural code for microwave thermotherapy published in the second quarter not only acknowledged Targis transurethral microwave therapy as a valid medical treatment for BPH, but also established reimbursement for the cost of a Targis procedure and the means by which physicians can bill a third party payer for their professional fee.

Over the last year, Medicare carriers in 49 states have issued favorable reimbursement coverage decisions for Targis therapy. This is an important milestone, since at least 60 percent of current Targis candidates are Medicare recipients. Medicare coverage is also a determinant of reimbursement by other third-party payers, including Blue Cross/Blue Shield as well as managed care organizations and private insurers.

With channels for reimbursement now initiated, the more complex issue of utilization is being addressed. Targis therapy is a new approach to treating BPH. It expands the urologist's treatment armamentarium beyond drugs and surgery, to include a new



l i m i t s

The social costs of BPH are high - relegating otherwise healthy men to a reclusive lifestyle. The Targis System represents a significant advance in treating BPH's bothersome symptoms. The 90-minute procedure is performed in an outpatient setting. Targis therapy is effective and durable with minimal discomfort, few side effects, fast recovery, and lasting good results - allowing men to resume an active and healthy lifestyle.



freedom

"I can't say enough good things about Targis therapy. Prior to it, I was up five times a night. I had a constant urge to urinate during the day, and my flow was weak. The treatment was easy - I played golf the next day. I'm functioning normally again, and I feel as good now as I ever have." ~ *Glenn Larson, age 72, retired, Bloomington, Minn., treated with the Targis System in May 1996*

Urologix has focused on gaining advocacy for the Targis System among key opinion leaders and leading urology centers worldwide. Controlled clinical studies and four years of strong follow-up data have prompted publication of favorable reports about Targis therapy in the field's most prestigious journals, including UROLOGY and the Journal of Urology.

noninvasive, non-pharmaceutical technology, which interjects uncertainty into the already uncertain environment that characterizes the practice of medicine today. Urologists, like all physicians, know implicitly that the future of medicine is moving towards effective and less costly noninvasive therapies like the Targis System, but many are reluctant to embrace change so early in the process.

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Recognizing that physicians learn by example and live by results, we have established a Quality Outcomes Initiative in clinic-based training centers, which teams experienced physicians with new Targis users. We have also developed a host of reimbursement, practice development and technical support services and tools. These value-added services are available to practitioners, clinics and payers through our in-house sales, marketing and product development group.

Excellence is the Urologix way and a point of differentiation in the marketplace. The Targis System is clearly gaining support as a potential first-line therapy for BPH among the best practitioners in the field — a prerequisite to capturing the collective attention of the wider urology community.

FACING CHANGE IN THE CHANGING FACE OF PATIENTS Every day in the United States, more than 11,000 men turn 50. This major demographic phenomenon signals that Baby Boomers are coming of age with far-reaching implications and huge rewards for those who understand the dynamics of this market segment. Boomers — long characterized as independent thinkers, comfortable with technology, more willing to question authority, less likely to acquiesce to the status quo or the vagaries of advancing age, and generally better consumers than their fathers or grandfathers — may well drive demand for effective, cost-efficient, noninvasive therapies like the Targis System.

As a company, we are working with physicians to proactively reach and educate this audience about BPH, with initiatives ranging from speakers' bureaus and community presentations to media kits and targeted public relations. We recognize that it is both good medicine and good business to do so — while also advancing the standard of care and effecting change for the better in the lives of thousands of men.



THE TARGIS™ SYSTEM CONTROL UNIT