

UROPLASTY INC  
Form 424B4  
November 20, 2007

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**Filed Pursuant to Rule 424(b)(4)  
Registration No. 333-146787**

**PROSPECTUS**

**1,466,400 SHARES**

**Common Stock**

We are selling 1,250,000 shares of common stock. Our common stock is traded on the American Stock Exchange under the symbol UPI. On November 19, 2007, the closing price of our common stock on the American Stock Exchange was \$3.96 per share.

**This investment is speculative and involves a high degree of risk. See Risk Factors on page 5 to read about factors you should consider before buying shares of the common stock.**

	<b>Per Share</b>	<b>Total</b>
Public offering price	\$ 3.50	\$ 5,132,400
Underwriting commission	\$ .21	\$ 307,944
Proceeds to Uroplasty before expenses	\$ 3.29	\$ 4,824,456

We have granted the underwriters a 30-day option to purchase up to an additional 219,960 shares of common stock to cover over-allotments, if any.

The underwriters expect to deliver the shares of common stock to purchasers on or about November 26, 2007.

**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.**

**Craig-Hallum Capital Group**

**Noble International Investments, Inc.**

Prospectus dated November 19, 2007

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**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information that is different from that contained in this prospectus. This prospectus may be used only where it is legal to sell these securities. The information in this prospectus is complete and accurate only as of the date on the front cover regardless of the time of any sale of shares.**

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**PROSPECTUS SUMMARY**

*This summary highlights the key information contained in this prospectus. Because it is a summary, it does not contain all the information you should consider before investing in our common stock. You should read carefully this entire prospectus. In particular, you should read the section entitled "Risk Factors" and the consolidated financial statements and the notes relating to those statements included elsewhere in this prospectus.*

**Overview**

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our primary focus is the commercialization of our Urgent PC<sup>®</sup> system, which we believe is the only FDA-approved non-surgical neurostimulation therapy for the treatment of overactive bladder symptoms. We also offer Macroplastique<sup>®</sup> Implants, a bulking agent for the treatment of urinary incontinence. We believe that physicians prefer our products because they offer an effective therapy for the patient, can be administered in office-based settings and, with reimbursement in place, provide the physicians a new profitable recurring revenue stream. We believe that patients prefer our products because they are non-surgical treatment alternatives that do not have the side effects associated with pharmaceutical treatment options.

**Market**

The field of neurostimulation, a form of therapy in which a low-voltage electrical current is used to treat medical conditions affecting parts of the nervous system, has grown dramatically in recent years. According to Medtech Insight, the U.S. market for neurostimulation devices is expected to grow from approximately \$628 million in 2006 to approximately \$2 billion in 2012, representing a compound annual growth rate in excess of 20%. FDA-approved neurostimulation devices are currently utilized to treat a range of indications, including voiding dysfunctions, chronic pain, epilepsy, essential tremor, Parkinson's disease, hearing loss and depression. These devices are implanted in the body or used in a non-invasive manner to stimulate different parts of the nervous system, including the spinal cord, sacral nerves and vagus nerve, among other areas. We believe the neurostimulation market represents a significant opportunity for us in the treatment of overactive bladder symptoms.

Voiding dysfunctions affect urinary control and can result in uncontrolled bladder sensations (overactive bladder) or unwanted leakage (urinary incontinence). Overactive bladder (OAB) is a prevalent and challenging urologic problem affecting an estimated 34 million Americans. 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. AHCPR estimates the total cost of treating incontinence (management and curative approaches) of all types in the United States is \$16 billion. Historically, only a small percentage of the patients suffering from these disorders have sought treatment. In recent years, however, the number of people seeking treatment has grown as a result of the publicity associated with new minimally invasive treatment alternatives.

When patients seek treatment, physicians generally assess the severity of the symptoms as mild, moderate or severe. Regardless of the degree of severity, however, patients will often consider drug therapy and minimally invasive treatment first. We believe that our company is uniquely positioned because we offer office-based, minimally invasive solutions.

**Our Strategy**

Our goal is to become the leading provider of non-surgical neurostimulation solutions for patients who suffer from OAB symptoms. We also plan to market other innovative products to physicians focused on office-based procedures for the treatment of urinary incontinence. We believe that, with our Urgent PC and Macroplastique products, we will increasingly garner the attention of key physicians, our

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independent sales representatives and distributors to grow revenue. The key elements of our strategy are to:

Educate physicians about the benefits of our Urgent PC neurostimulation system.

Build patient awareness of office-based solutions

Focus on office-based solutions for physicians.

Increase market coverage in the United States sales and internationally.

Develop, acquire or license new products.

## **Our Products**

The Urgent PC neurostimulation system is a minimally invasive device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. The Urgent PC system uses percutaneous tibial nerve stimulation to deliver an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. We have received regulatory approvals 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.

Macroplastique is a minimally invasive, implantable soft tissue bulking product 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 FDA pre-market approval for the use of Macroplastique to treat female stress incontinence. We began marketing this product in the United States in early 2007.

## **Sales and Marketing**

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 personnel 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 overactive bladder symptoms and incontinence.

## **Corporate Information**

Our company was incorporated in Minnesota in 1992. Our headquarters are located at 5420 Feltl Road, Minnetonka, Minnesota, 55343. Our telephone number is (952) 426-6140. We maintain a web site at [www.uroplasty.com](http://www.uroplasty.com). Information contained on our web site is not part of this prospectus.

Urgent® PC, Macroplastique®, Bioplastique®, PTQ®, VOX® and I-Stop™ are trademarks we own or license. This prospectus also refers to trademarks and tradenames of other organizations.

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**The Offering**

Common stock offered:	1,466,400 shares
Common stock outstanding before offering:	13,450,140 shares as of October 5, 2007
Common stock to be outstanding after offering:	14,916,540 shares
Overallotment option:	219,960 shares
Use of proceeds:	We expect to use the net proceeds from this offering to expand our sales and marketing organization in the United States, to conduct clinical studies to support our marketing efforts and for working capital purposes. Our management will have broad discretion in determining the specific timing and uses of the offering proceeds.
Risk factors:	Our business is subject to a number of risks which you should consider before investing in our company. For a discussion of the significant risks associated with our business, please read the section entitled Risk Factors beginning on page 5.
Trading symbol:	Our common stock is traded on the American Stock Exchange under the symbol UPI.

The number of shares of common stock outstanding as of October 5, 2007 and to be outstanding after this offering exclude:

2,033,100 shares of common stock subject to outstanding options, at a weighted average exercise price of \$4.01 per share;

2,116,478 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$3.81 per share; and

529,500 shares of common stock reserved for issuance under our 2006 Stock and Incentive Plan.

Except as otherwise indicated, all information in this prospectus assumes no exercise of the underwriters overallotment option.

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The following tables present our summary consolidated financial data for our fiscal years ended March 31, 2007 and 2006, which have been derived from our audited consolidated financial statements. The financial data for our six months ended September 30, 2007 and 2006 have been derived from our unaudited consolidated financial statements which, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and include all normal and recurring adjustments and accruals necessary for a fair presentation of such information. You should read this information in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	<b>Fiscal Year Ended March 31,</b>		<b>Six Months Ended</b>	
	<b>2006</b>	<b>2007</b>	<b>September 30,</b>	<b>2007</b>
			<b>(Unaudited)</b>	
<b>Consolidated Statements of Operations</b>				
<b>Data:</b>				
Net sales	\$ 6,142,612	\$ 8,311,001	\$ 3,524,980	\$ 5,988,217
Cost of goods sold	1,837,716	2,590,535	1,008,372	1,263,253
Gross profit	4,304,896	5,720,466	2,516,608	4,724,964
Operating expenses:				
General and administrative	2,856,486	3,095,989	1,658,287	1,955,806
Research and development	3,324,201	2,276,526	1,333,363	933,122
Selling and marketing	3,399,896	5,216,765	2,536,283	3,607,372
Amortization of intangibles	102,496	103,511	53,112	423,003
Total operating expenses	9,683,079	10,692,791	5,581,045	6,919,303
Operating loss	(5,378,183)	(4,972,325)	(3,064,437)	(2,194,339)
Other income (expense)	788,597	141,771	(317,781)	106,952
Loss before income taxes	(4,589,586)	(4,830,554)	(3,382,218)	(2,087,387)
Income tax expense (benefit)	(46,873)	146,336	17,911	137,940
Net loss	\$ (4,542,713)	\$ (4,976,890)	\$ (3,400,129)	\$ (2,225,327)
Basic and diluted net loss per common share	\$ (0.67)	\$ (0.58)	\$ (0.46)	\$ (0.17)
Basic and diluted weighted average common shares	6,746,412	8,591,454	7,376,900	13,162,862
		<b>March 31,</b>	<b>September 30,</b>	
		<b>2006</b>	<b>2007</b>	<b>2007</b>
				<b>(Unaudited)</b>



**Consolidated Balance Sheet Data:**

Cash and cash equivalents	\$ 1,563,433	\$ 3,763,702	\$ 3,309,747
Short-term investments	1,137,647	3,000,000	2,400,000
Net working capital	2,667,053	7,207,175	6,529,958
Property, plant and equipment, net	1,079,438	1,431,749	1,510,722
Total assets	6,401,244	11,046,444	14,961,804
Long-term debt, less current maturities	389,241	427,382	413,064
Shareholders' equity	3,407,050	7,803,047	11,842,886

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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 prospectus 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.*

**Risks Relating to Our Company and Industry**

*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 September 30, 2007, we had an accumulated deficit of approximately \$18.2 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 to 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 sufficient revenue from the sale of our products to be profitable.

*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 personnel and a network of independent sales representatives. In the United Kingdom, we have direct sales personnel. Our marketing organization supports our U.S. and U.K. sales and international 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 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 U.S. and the U.K., we sell our products 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 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 may 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 system, 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, cost-effectiveness and third party reimburseability 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 may decline or we may be unable to increase our revenues and be profitable.

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***To date, we have been primarily dependent on sales of one product line and our business may suffer if sales of this product line decline.***

To date, we have been 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 demand for our Macroplastique products declines, our revenues and business prospects may suffer.

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

Our future liquidity and capital requirements will depend on numerous factors including: the timing and cost 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 may need to raise additional financing to support our operations and planned growth activities in the future. 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 cannot assure you that we will obtain additional financing on acceptable terms, or at all.

***The size and resources of our competitors may allow them to compete more effectively than we can, which could adversely affect our potential profitability.***

Our products compete against similar medical devices and other treatment methods, including drugs, for treating voiding dysfunctions. Many of our competitors have significantly greater financial, research and development, manufacturing and marketing resources than we have. Our competitors could use these resources to develop or acquire products that are safer, more effective, less invasive, less expensive or more readily accepted than our products. Their products could make our technology and products obsolete or noncompetitive. Our competitors could also devote greater resources to the marketing and sale of their products and adopt more aggressive pricing policies than we can. If we are not able to compete effectively, then we may not be profitable.

***Our products and facilities are subject to extensive regulation, with which compliance is costly and which exposes us to penalties for non-compliance.***

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. We cannot assure you that we will obtain approval for any future products or that we will maintain approval to sell any of our existing products. 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;

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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 revenues from our international operations and our results of operations may be adversely affected.

In addition, our business and properties are subject to federal, state and local laws and regulations relating to the protection of the environment, natural resources and worker health and safety and the use, management, storage, and disposal of hazardous substances, wastes, and other regulated materials. The costs of complying with these various environmental requirements, as they now exist or may be altered in the future, could adversely affect our financial condition and results of operations.

***The marketing of our products requires a significant amount of time and expense and we may not have the resources to successfully market our products, which would adversely affect our business and results of operations.***

The marketing of our products requires a significant amount of time and expense in order to identify the physicians who may use our products, invest in training and education and employ a sales force that is large enough to interact with the targeted physicians. We may not have adequate resources to market our products successfully against larger competitors who have more resources than we do. If we cannot market our products successfully, our business and results of operations would be adversely affected.

***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

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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; and/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 discover or independently develop similar proprietary information.

***Product liability claims could adversely affect our business and results of operations.***

The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Our existing products were developed relatively recently and defects or risks that we have not yet identified may give rise to product liability claims. Our existing \$2 million of worldwide



product liability insurance coverage would likely 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

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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 continue to scale-up our 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 loss or interruption of products or materials from any of our key suppliers could slow down the manufacture and distribution of our products, which would limit our ability to generate sales and revenues.***

We currently purchase several products, and 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 products and 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 products or 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 of our products by the FDA, European Union or other relevant authorities could be delayed or denied and our sales and revenues will suffer.***

Approval of our products could be delayed by the FDA, European Union or other related authorities if our manufacturing facilities do not comply with applicable manufacturing requirements. The FDA's Quality System Regulations impose 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.



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Even with approval to market our products in the United States, European Union 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.

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

Our two largest customers each accounted 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. We face the risk that one or both 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 results of operations and financial condition.

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

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

### ***We are dependent on the availability of third-party reimbursement for our revenues.***

Our success depends on the availability of reimbursement for the cost of our products from third-party payors, such as government health authorities, private health insurance plans and managed care organizations. There is no uniform policy for reimbursement in the United States and foreign countries. As a relatively new therapy, PTNS using the Urgent PC system has not been assigned a reimbursement code unique to the technology. A number of practitioners are using an existing reimbursement code that closely describes the procedure. In addition, Aetna and Blue Cross Blue Shield of Minnesota, Delaware, Northern Virginia, District of Columbia and Maryland have published policies providing coverage for PTNS under an existing reimbursement code. However, we cannot assure you that adequate coverage and reimbursement will be provided for the Urgent PC system in the future by third-party payors. Accordingly, changes in the extent or type of coverage or a reduction in reimbursement rates under any or all third-party reimbursement programs may cause a decline in purchases of our products, which would materially adversely affect the market for our products. Alternatively, we might respond to reduced reimbursement rates by reducing the prices of our products, which could also reduce our revenues.

### ***If physicians do not recommend and endorse our products, our sales may decline or we may be unable to increase our sales and profits.***

In order for us to sell our products, physicians must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from physicians. Acceptance of our products depends on educating the medical community as to the distinctive characteristics, perceived benefits, safety, clinical efficacy, cost-effectiveness and third party reimburseability of our products compared to products of our competitors, and on training physicians in the proper application of our products. If we



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are not successful in obtaining the recommendations or endorsements of physicians for our products, our sales may decline or we may be unable to increase our sales and profits.

***Our business strategy relies on assumptions about the market for our products, which, if incorrect, would adversely affect our business prospects and profitability.***

We are focused on the market for minimally invasive therapies used to treat voiding dysfunctions. We believe that the aging of the general population will continue and that these trends will increase the need for our products. However, the projected demand for our products could materially differ from actual demand if our assumptions regarding these trends and acceptance of our products by the medical community prove to be incorrect or do not materialize. Actual demand for our products could also be affected if drug therapies gain more widespread acceptance as a viable alternative treatment, which in each case would adversely affect our business prospects and profitability.

***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 revenues 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 system. 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;

the imposition of costly and lengthy new export licensing requirements;



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the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;

political and economic instability;

fluctuations in the value of the U.S. dollar relative to foreign currencies;

a shortage of high-quality sales people and distributors;

loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;

changes in duties and tariffs, license obligations and other non-tariff barriers to trade;

the imposition of new trade restrictions;

the imposition of restrictions on the activities of foreign agents, representatives and distributors;

scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles;

difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;

difficulties in enforcing or defending intellectual property rights; and

exposure to different legal and political standards due to our conducting business in approximately 40 countries.

We cannot assure you that one or more of these factors will not harm our business. Any material decrease in our international sales would adversely impact our net sales, results of operations and financial condition. Our international sales are predominately in Europe. In Europe, health care regulation and reimbursement for medical devices vary significantly from country to country. This changing environment could adversely affect our ability to sell our products in some European countries.

***Fluctuations in foreign exchange rates could negatively impact our results of operations.***

Because our international sales are denominated primarily in euros, currency fluctuations in countries where we do business may render our products less price competitive than those of competing companies whose sales are



denominated in weaker currencies. We report our financial results in U.S. dollars, and fluctuations in the value of either the dollar or the currencies in which we transact business can have a negative impact on our results of operations and financial condition. Consequently, we have exposure to foreign currency exchange risks. We do not hedge any of our foreign currency risk.

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***Proposals to modify the health care system in the U.S. or other countries could affect the pricing of our products. If we cannot sell our products at the prices we plan to, our margins and profitability could be adversely affected.***

Proposals to modify the current health care system in the United States to improve access to health care and control its costs are continually being considered by the federal and state governments. We anticipate that the U.S. Congress and state legislatures will continue to review and assess alternative health care reform proposals. We cannot predict whether these reform proposals will be adopted, when they may be adopted or what impact they may have on us if they are adopted. Any spending decreases or other significant changes in government programs such as Medicare could adversely affect the pricing of our products.

Like the United States, foreign countries have considered health care reform proposals and could materially alter their government-sponsored health care programs by reducing reimbursement rates. Any reduction in reimbursement rates under United States or foreign health care programs could negatively affect the pricing of our products. If we are not able to charge a sufficient amount for our products, our margins and our profitability will be adversely affected.

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

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

earthquake, fire, flood and other natural disasters;

terrorist attacks and attacks by computer viruses or hackers; and

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

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

***If we lose the services of our chief executive officer or other key personnel, we may not be able to manage our operations and meet our strategic objectives.***

Our future success depends, in large part, on the continued service of our senior management. We have no key person insurance with respect to any of our senior managers, and any loss or interruption of their services could significantly reduce our ability to effectively manage our operations and implement our strategy. Also, we depend on the continued service of key managerial, scientific and technical personnel. Further, we depend on our ability to continue to attract and retain additional highly qualified medical device sales personnel. Any loss or interruption of the services of our other key personnel could also significantly reduce our ability to effectively manage our operations and meet our strategic objectives because we cannot assure you that we would be able to find an appropriate replacement should the need arise.

***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.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other products or companies for stock. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, 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/or

the acquisition may disrupt our ongoing business, distract our management and divert our resources.

## **Risks Relating to Our Common Stock and This Offer**

*You may be unable to sell the common stock you purchase in this offering.*

There is only a limited trading market for our common stock, which is quoted on the AMEX. Transactions in our common stock may lack the volume, liquidity and orderliness necessary to maintain a liquid and active trading market. Accordingly, an investor should consider the potential lack of liquidity before investing in our common stock.

*Our stock price may fluctuate and be volatile.*

The market price of our common stock may be subject to significant fluctuation due to the following factors, among others:

variations in our quarterly financial results;

developments regarding regulatory clearances or approvals of our products;

market acceptance of our products;

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

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

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

developments in U.S. or international reimbursement systems;

changes in accounting standards, policies, guidance or interpretations;

sales of substantial amounts of our stock by existing shareholders; and  
general economic or market conditions.

The stock market in recent years has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of affected companies. These broad market fluctuations may cause the price of our common stock to fall abruptly or remain significantly depressed.

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***Future sales of our common stock in the public market could lower our share price.***

The market price of our common stock could decline due to sales by our existing shareholders of a large number of shares of our common stock or the perception that these sales could occur. These sales could also make it more difficult for us to raise capital through the sale of common stock at a time and price we deem appropriate.

We have a significant number of equity instruments outstanding subject to conversion to our common stock. As of October 5, 2007, we had 2,033,100 shares of our common stock subject to outstanding options (of which 1,558,263 are exercisable) and 2,116,478 shares of our common stock subject to outstanding warrants. Further, in April 2007, we issued 1,417,144 shares of our common stock to purchase from CystoMedix, Inc. certain intellectual property assets related to the Urgent PC system. The shares issued to CystoMedix will become eligible for public resale beginning in April 2008.

***We will be exposed to risks relating to evaluations of controls required by Section 404 of the Sarbanes-Oxley Act.***

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We are evaluating our internal controls systems to allow management to report on, and our independent auditors to attest to, our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement management attestation requirements relating to internal controls and all other aspects of Section 404 by our March 31, 2008 deadline and auditor attestation requirements by March 31, 2009, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, we may be subject to sanctions or investigation by regulatory authorities, including the SEC. This type of action could adversely affect our financial results or investors confidence in our company and our ability to access capital markets and could cause our stock price to decline. In addition, the controls and procedures that we will implement may not comply with all of the relevant rules and regulations of the SEC. If we fail to develop and maintain effective controls and procedures, we may be unable to provide the required financial information in a timely and reliable manner. Further, if we acquire any company in the future, we may incur substantial additional costs to bring the acquired company's systems into compliance with Section 404.

***Our corporate documents and Minnesota law contain provisions that could discourage, delay or prevent a change in control of our company.***

Provisions in our articles of incorporation may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our articles of incorporation provide for a staggered board of directors, whereby directors serve for three year terms, with approximately one third of the directors coming up for reelection each year. Having a staggered board will make it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

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

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**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements. All statements other than statements of historical facts are forward-looking statements, including statements regarding our future financial position, business strategy, and plans and objectives for future operations and products. The words may, will, believe, expect, estimate, continue, intend and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, business operations and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including, among other things:

the highly competitive nature of the markets in which we sell our products;

regulatory hurdles that may prevent, delay or make more expensive our introduction of products;

the failure to continue developing innovative products;

the loss of our customers;

increases in prices for raw materials or the loss of key supplier contracts;

employee slowdowns, strikes or similar actions;

product liability claims exposure;

risks in connection with our operations outside the United States;

conditions and changes in the medical device industry generally;

the failure in protecting our intellectual property;

exposure to competitors' assertions of intellectual property claims;

the failure to retain senior management or replace lost senior management;

changes in U.S. generally accepted accounting principles;

changes in general economic and business conditions;

changes in currency exchange rates and interest rates;

introduction of competing products;

lack of acceptance of new products;

competitive pressures on the transactional sales and margins, and competition from new market participants for our sales;

adverse changes in applicable laws or regulations;



the incurrence of additional debt, contingent liabilities and expenses in connection with future acquisitions;

the failure to integrate effectively newly acquired operations; and

the absence of expected returns from the amount of intangible assets we have recorded.

We believe that the above factors are important, but not necessarily all of the important factors that could cause actual results to differ materially from those expressed in any forward-looking statement. Unpredictable or unknown factors could also have material adverse effects on us. Since our actual results, performance or achievements could differ materially from those expressed in, or implied by, the forward-looking statements, we cannot give any assurance that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our

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results of operations and financial condition. All forward-looking statements included in this prospectus are expressly qualified in their entirety by the foregoing cautionary statements. You should not place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. We do not undertake any obligation to update any of the forward-looking statements, except as may be required under federal securities laws.

**USE OF PROCEEDS**

We estimate that we will receive net proceeds from this offering of approximately \$4.7 million (or \$5.4 million if the underwriters' over-allotment option is exercised in full), based on the public offering price of \$3.50 per share, after deducting the underwriting commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering primarily to expand our sales and marketing organization in the United States, to conduct clinical studies to support our marketing efforts and for working capital purposes. We have not made a specific allocation for the use of the net proceeds, and we will have broad discretion in determining the specific timing and use of any offering proceeds. The exact amount and timing of our expenditures will depend on several factors, including the amount of proceeds raised in this offering. Investors will be relying on the judgment of our management regarding the application of the net proceeds in this offering.

Until we use our net proceeds of the offering, we will invest the funds in short-term, investment grade, interest-bearing instruments or securities.

**Table of Contents****PRICE RANGE OF COMMON STOCK**

Our common stock has been traded on the American Stock Exchange under the symbol UPI since October 3, 2005. On November 19, 2007, the closing price of our common stock on the American Stock Exchange was \$3.96 per share. Previously, our common stock was quoted on the OTC Bulletin Board under the symbol UPST.OB.

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

<b>Fiscal Year 2008</b>	<b>Low</b>	<b>High</b>
April 1 - June 30, 2007	\$ 3.20	\$ 5.00
July 1 - September 30, 2007	\$ 3.70	\$ 4.50
October 1 - November 19, 2007	\$ 3.57	\$ 4.26

<b>Fiscal Year 2007</b>	<b>Low</b>	<b>High</b>
April 1 - June 30, 2006	\$ 1.70	\$ 2.60
July 1 - September 30, 2006	\$ 1.62	\$ 3.80
October 1 - December 31, 2006	\$ 2.05	\$ 3.40
January 1 - March 31, 2007	\$ 2.36	\$ 3.48

<b>Fiscal Year 2006</b>	<b>Low</b>	<b>High</b>
April 1 - June 30, 2005	\$ 3.91	\$ 4.90
July 1 - September 30, 2005	\$ 2.60	\$ 5.80
October 1 - December 31, 2005	\$ 2.60	\$ 3.80
January 1 - March 31, 2006	\$ 2.30	\$ 3.14

As of October 5, 2007, we had 512 holders of record of our common stock. Record ownership includes nominees who may hold securities on behalf of multiple beneficial owners.

**DIVIDEND POLICY**

We have never paid cash dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future. We intend to retain future earnings, if any, for the development and expansion of our business.

**Table of Contents****SELECTED FINANCIAL DATA**

The following tables present our summary consolidated financial data for our fiscal years ended March 31, 2007 and 2006, which have been derived from our audited consolidated financial statements. The financial data for our six months ended September 30, 2007 and 2006 have been derived from our unaudited consolidated financial statements which, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and include all normal and recurring adjustments and accruals necessary for a fair presentation of such information. You should read this information in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	<b>Fiscal Year Ended March 31,</b>		<b>Six Months Ended</b>	
	<b>2006</b>	<b>2007</b>	<b>2006</b>	<b>2007</b>
			<b>(Unaudited)</b>	
<b>Consolidated Statements of Operations</b>				
<b>Data:</b>				
Net sales	\$ 6,142,612	\$ 8,311,001	\$ 3,524,980	\$ 5,988,217
Cost of goods sold	1,837,716	2,590,535	1,008,372	1,263,253
Gross profit	4,304,896	5,720,466	2,516,608	4,724,964
Operating expenses:				
General and administrative	2,856,486	3,095,989	1,658,287	1,955,806
Research and development	3,324,201	2,276,526	1,333,363	933,122
Selling and marketing	3,399,896	5,216,765	2,536,283	3,607,372
Amortization of intangibles	102,496	103,511	53,112	423,003
Total operating expenses	9,683,079	10,692,791	5,581,045	6,919,303
Operating loss	(5,378,183)	(4,972,325)	(3,064,437)	(2,194,339)
Other income (expense)	788,597	141,771	(317,781)	106,952
Loss before income taxes	(4,589,586)	(4,830,554)	(3,382,218)	(2,087,387)
Income tax expense (benefit)	(46,873)	146,336	17,911	137,940
Net loss	\$ (4,542,713)	\$ (4,976,890)	\$ (3,400,129)	\$ (2,225,327)
Basic and diluted net loss per common share	\$ (0.67)	\$ (0.58)	\$ (0.46)	\$ (0.17)
Basic and diluted weighted average common shares	6,746,412	8,591,454	7,376,900	13,162,862
		<b>March 31,</b>	<b>September 30,</b>	
		<b>2006</b>	<b>2007</b>	<b>2007</b>

(Unaudited)

**Consolidated Balance Sheet Data:**

Cash and cash equivalents	\$ 1,563,433	\$ 3,763,702	\$ 3,309,747
Short-term investments	1,137,647	3,000,000	2,400,000
Net working capital	2,667,053	7,207,175	6,529,958
Property, plant and equipment, net	1,079,438	1,431,749	1,510,722
Total assets	6,401,244	11,046,444	14,961,804
Long-term debt, less current maturities	389,241	427,382	413,064
Shareholders' equity	3,407,050	7,803,047	11,842,886

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION  
AND RESULTS OF OPERATIONS**

*You should read the following discussion of our financial condition and the results of operations in conjunction with our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those suggested by our forward-looking statements due to various reasons, including those discussed in the section entitled Risk Factors.*

**Overview**

We are a medical device company that develops, manufactures and markets innovative proprietary products for the treatment of voiding dysfunctions. Our primary focus is the commercialization of our Urgent PC system, which we believe is the only FDA-approved non-surgical neurostimulation therapy for the treatment of overactive bladder symptoms. We also offer Macroplastique, a bulking agent for the treatment of urinary incontinence. We believe that physicians prefer our products because they offer an effective therapy for the patient, can be administered in office-based settings and, with reimbursement in place, provide the physicians a new profitable recurring revenue stream. We believe that patients prefer our products because they are non-surgical treatment alternatives that do not have the side effects associated with pharmaceutical treatment options.

**Strategy**

Our goal is to become the leading provider of non-surgical neurostimulation solutions for patients who suffer from OAB symptoms. We also plan to market other innovative products to physicians focused on office-based procedures for the treatment of urinary incontinence. We believe that, with our Urgent PC and Macroplastique products, we will increasingly garner the attention of key physicians, independent sales representatives and distributors to grow revenue. The key elements of our strategy are to:

- Educate physicians about the benefits of Urgent PC.
- Build patient awareness of office-based solutions.
- Focus on office-based solutions for physicians
- Increase market coverage in the United States and internationally.
- Develop, license or acquire new products.

**Our Products**

The Urgent PC neurostimulation system is a minimally invasive device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. The treatment can be administered by qualified office-based staff under the supervision of a physician. The system 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 sale of the Urgent PC system in the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we have launched the Urgent PC system for sale in those markets. We launched our second generation Urgent PC system in late 2006.

Macroplastique is a minimally invasive, implantable soft tissue bulking product 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 FDA pre-market approval for the use of Macroplastique to treat female stress incontinence. We began marketing this product in the United States in early 2007.

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### **Sales and Marketing**

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 overactive bladder symptoms and incontinence.

### **Critical Accounting Policies**

We prepare our consolidated financial statements in accordance with U.S. generally accepted accounting principles, which require us to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing our consolidated financial statements, we have made our best estimates and judgments of certain amounts, giving due consideration to materiality. We believe that of our significant accounting policies, the following are particularly important to the portrayal of our results of operations and financial position. They may require the application of a higher level of judgment by our management, and as a result are subject to an inherent degree of uncertainty.

*Revenue Recognition.* The SEC's Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition in Financial Statements*, provides guidance on the application of generally accepted accounting principles to selected revenue recognition issues. We believe our revenue recognition policies comply with SAB 104. We market and distribute our products primarily through our direct and independent sales organization in the United States and the United Kingdom, and primarily through distributors in our other markets. We recognize revenue upon shipment of product to our distributors and direct customers. We have no customer acceptance provisions or installation obligations. Our sales terms to our distributors and customers provide no right of return outside of our standard warranty, and payment terms consistent with industry standards apply. Sales terms and pricing to our distributors are governed by the respective distribution agreements. Our distribution partners purchase our products to meet sales demand of their end-user customers as well as to fulfill their internal requirements associated with the sales process and, if applicable, contractual purchase requirements under the respective distribution agreements. Internal and other requirements include purchases of products for training, demonstration and evaluation purposes, clinical evaluations, product support, establishing inventories, and meeting minimum purchase commitments. As a result, the level of our net sales during any period is not necessarily indicative of our distributors' sales to end-user customers during that period, which we estimate are not substantially different than our sales to those distributors in each of the last two years. Our distributors' level of inventories of our products, their sales to end-user customers and their internal product requirements may impact our future revenue growth.

*Accounts Receivable.* We carry our accounts receivable at the original invoice amount less an estimate made for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts based on customer financial health, and both historical and expected credit loss experience. We write off our accounts receivable when we deem them uncollectible. We record recoveries of accounts receivable previously written off when received.

*Inventories.* We state inventories at the lower of cost or market using the first-in, first-out method. We provide lower of cost or market reserves for slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. While we expect our sales to grow, a reduction in sales could reduce the demand for our products and may require additional inventory reserves.



*Foreign Currency Translation/Transactions.* The financial statements of our foreign subsidiaries were translated in accordance with the provisions of SFAS No. 52 Foreign Currency Translation. Under

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this Statement, we translate all assets and liabilities using period-end exchange rates, and we translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders' equity. We recognize foreign currency transaction gains and losses in the statement of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates, resulting in an increase in the volatility of our consolidated statements of operations. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders' equity.

*Impairment of Long-Lived Assets.* Long-lived assets at June 30, 2007 consist of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. We measure the recoverability of assets to be held and used by a comparison of the carrying amount of assets to future undiscounted net cash flows expected to be generated by the assets. If we consider such assets impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We report assets to be disposed of at the lower of the carrying amount or fair value less costs to sell.

*Share-Based Compensation.* In December 2004, the Financial Accounting Standards Board, or FASB, published Statement No. 123 (revised 2004), *Share-Based Payment* (SFAS 123(R)). SFAS 123(R) requires that we recognize the compensation cost relating to share-based payment transactions, including grants of employee stock options, in our financial statements, based on the fair value of the equity or liability instruments issued. SFAS 123(R) covers a wide range of share-based compensation arrangements, including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans.

SFAS 123(R) requires us to measure the cost of employee services received in exchange for stock options based on the grant-date fair value of the award, and to recognize the cost over the period we require our employee to provide services for the award. We adopted FAS 123(R) on April 1, 2006 using the modified prospective transition method. We calculated the pro forma compensation costs presented previously and in our prior filings using a Black-Scholes option pricing model.

*Defined Benefit Pension Plans.* We have a liability attributed to defined benefit pension plans we offered to certain former and current employees prior to April 2005. We pay premiums to an insurance company to fund annuities and are responsible for funding additional annuities based on continued service and future salary increases for these employees' pension benefit. The liability is dependent upon numerous factors, assumptions and estimates, and the continued benefit costs we incur may be significantly affected by changes in key actuarial assumptions such as the discount rate, compensation rates, or retirement dates used to determine the projected benefit obligation. In addition, changes made to the provisions of the plans may impact current and future benefit costs. In accordance with accounting rules, changes in benefit obligations associated with these factors may not be immediately recognized as costs on the income statement, but are recognized in future years over the remaining average service period of plan participants.

*Income Taxes.* We recognize deferred tax assets and liabilities for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. We measure deferred tax assets and liabilities using enacted tax rates we expect to apply to taxable income in the years in which we expect to recover or settle those temporary differences. As of March 31, 2007, we had generated approximately \$18 million in U.S. net operating loss carryforwards that we cannot use to offset taxable income in foreign jurisdictions. We recognize a valuation allowance when we determine it is more likely than not that we will not realize all or a portion of our deferred tax assets. We have established a valuation allowance for United States and certain foreign deferred tax assets due to the uncertainty that we will generate enough income in those taxing jurisdictions to utilize the assets.



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In addition, future utilization of NOL carryforwards is subject to certain limitations under Section 382 of the Internal Revenue Code. This section generally relates to a 50 percent change in ownership of a company over a three-year period. We believe that the issuance of our common stock in prior public offerings and stock issuances has resulted in an ownership change under Section 382. Accordingly, our ability to use NOL tax attributes generated prior to December 2006 will likely be limited.

**Results of Operations*****Six Months Ended September 30, 2007 Compared to Six Months Ended September 30, 2006***

*Net Sales:* During the six months ended September 30, 2007, net sales were \$6.0 million, representing a \$2.5 million or a 70% increase compared to net sales of \$3.5 million for the six months ended September 30, 2006. Excluding the translation impact of fluctuations in foreign currency exchange rates, sales increased by approximately 64%. We attribute the vast majority of this growth in sales to our customers in the U.S. as a result of our expanded U.S. sales organization, and the continued growth in sales of our Urgent PC system. Also, in the six months ended September 30, 2007, sales of our Macroplastique product outside of the U.S. increased, which we attribute to our increased marketing focus.

Sales to customers in the U.S. increased to \$2.2 million during the six months ended September 30, 2007, from \$357,000 in the same period last year. We attribute this growth primarily to the Urgent PC system and the expanded sales organization. During the six months ended September 30, 2007, we had minimal sales of our Macroplastique product in the U.S., which we launched in the U.S. early in 2007, and the I-Stop product, which we discontinued selling in the United States.

Sales to customers outside the U.S. for the six months ended September 30, 2007 were \$3.8 million, representing a \$592,000 or 19% increase, compared to \$3.2 million for the six months ended September 30, 2006. Excluding the translation impact of fluctuations in foreign currency exchange rates, sales increased by approximately 12%. We attribute the increase primarily to the increase in our Macroplastique sales.

*Gross Profit:* Gross profit was \$4.7 million and \$2.5 million for the six months ended September 30, 2007 and 2006, respectively, or 79% and 71% of net sales in the respective periods. We attribute the lower gross profit percentage for the six months ended September 30, 2006 primarily to lower manufacturing capacity utilization in the three months ended June 30, 2006 due to the decline in Macroplastique sales and duplicate manufacturing facilities in the U.S. This decline was offset partially by increased manufacturing capacity utilization in the three months ended September 30, 2006, when we stepped up production to build inventory to meet our needs for the transition period while relocating our manufacturing operations to our new corporate headquarters in Minnetonka, Minnesota. We attribute the higher gross profit percentage for the six months ended September 30, 2007 to a favorable impact of approximately four percentage points due to the increase in manufacturing capacity utilization as a result of increased sales, savings of approximately \$180,000 due to the discontinuation of manufacturing at our Eindhoven, The Netherlands facility, and approximately one percentage point impact due to an increase in the average selling price in the U.S. of the lead sets used with our Urgent PC system. We expect the gross profit percentage to be in the range of 73% to 78%, excluding any unusual charges, in the remaining quarters of the current fiscal year, although change in the product mix we sell can shift the overall gross margin.

*General and Administrative Expenses (G&A):* G&A expenses increased from \$1.7 million during the six months ended September 30, 2006 to \$2.0 million during the same period in 2007. Included in the six-month period ended September 30, 2006 is a \$392,000 non-cash, SFAS 123 (R) charge for share-based employee compensation, compared with a charge of \$464,000 in the six-month period ended September 30, 2007. Excluding share-based compensation charges, G&A expenses increased by \$226,000, primarily because of an increase in personnel-related costs and

consulting fees, offset by a reduction in rent expense for our leased facilities in the United Kingdom and the U.S.

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*Research and Development Expenses (R&D):* R&D expenses decreased from \$1.3 million during the six months ended September 30, 2006 to \$933,000 during the same period in 2007. We attribute the decrease primarily to reduced consulting expense of \$233,000 and a decrease in personnel-related costs of \$131,000. During the six months ended September 30, 2006, we incurred consulting expense associated with the development of our second generation Urgent PC system and preparation for a clinical study.

*Selling and Marketing Expenses (S&M):* S&M expenses increased from \$2.5 million during the six months ended September 30, 2006 to \$3.6 million during the same period in 2007. We attribute the increase to a \$353,000 increase in compensation-related costs, primarily as a result of increased salaries and bonuses, a \$444,000 increase in commissions for sales agents and independent sales representatives, and an increase in other costs to support our expanded sales organization and marketing activities.

*Amortization of Intangibles:* Amortization of intangibles increased from \$53,000 during the six months ended September 30, 2006 to \$423,000 during the same period in 2007. In April 2007, we acquired from CystoMedix, Inc., certain intellectual property assets related to the Urgent PC system for \$4.7 million. We began amortizing the intellectual property assets acquired over six years starting in April 2007.

*Other Income (Expense):* Other income (expense) includes interest income, interest expense, warrant expense, foreign currency exchange gains and losses and other non-operating costs when incurred. Other income (expense) was \$107,000 and \$(318,000) for the six months ended September 30, 2007 and 2006, respectively, with \$373,000 of the change resulting from a warrant expense in the six months ended September 30, 2006.

In May 2002, we conducted a public rights offering. In the rights offering, we issued to those shareholders who exercised their rights three shares of our common stock and a warrant, exercisable through July 2004, to purchase an additional share of our common stock. We registered with the SEC the issuance of the shares, the warrants and the shares underlying the warrants. In July 2004, we suspended the right to exercise the warrants shortly before their scheduled expiration date because we announced a planned restatement of our fiscal 2004 financial statements. In November 2004, we became current with our SEC filings. In April 2005, we chose to issue like-kind replacement warrants to the holders of the expired warrants. The terms for the replacement warrants required that we issue shares covered by a registration statement and maintain the effectiveness of the registration (by making timely SEC filings) for the warrant holders to receive registered shares upon exercise of the warrants. In April 2005, we recognized a liability and equity charge of \$1.4 million associated with the grant of these warrants, and subsequently recognized in other income (expense) the change in fair value of the warrants due to the change in the value of our common stock issuable upon exercise of these warrants. We determined the fair value of the warrants using the Black-Scholes option-pricing model. The period to exercise the warrants ended in March 2007. We recognized a net warrant expense of \$373,000 during the six months ended September 30, 2006.

We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the Euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between us and our foreign subsidiaries. We recognized foreign currency gains (losses) of \$(16,000) and \$30,000 for the six months ended September 30, 2007 and 2006, respectively.

*Income Tax Expense:* During the six months ended September 30, 2007 and 2006, our Dutch subsidiaries recorded income tax expense of approximately \$138,000 and \$18,000, respectively. During the six months ended September 30, 2007 and 2006, our U.S. organization recorded income tax expense of \$300 and \$0, respectively. We cannot use our U.S. net operating loss carry forwards to offset taxable income in foreign jurisdictions. Effective January 1, 2007, the maximum Dutch income tax rate is 25.5% for taxable income in excess of 60,000.



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*Non-GAAP Financial Measures.* The following table reconciles our financial results calculated in accordance to U.S. generally accepted accounting principles (GAAP) to non-GAAP financial measures that exclude non cash charges attributed to stock options under SFAS 123(R), and depreciation and amortization expenses from gross profit, operating expenses and operating loss. The non-GAAP financial measures used by management and disclosed by us are not a substitute for, or superior to, financial measures and consolidated financial results calculated in accordance with GAAP, and you should carefully evaluate our reconciliations to non-GAAP. We may calculate our non-GAAP financial measures differently from similarly titled measures used by other companies. Therefore, our non-GAAP financial measures may not be comparable to those used by other companies. We have described the reconciliations of each of our non-GAAP financial measures above to the most directly comparable GAAP financial measures.

Management uses our non-GAAP financial measures, and in particular non-GAAP operating loss, for internal managerial purposes because we believe such measures are one important indicator of the strength and the performance of our business because they provide a link to operating cash flow. We also believe that analysts and investors use such measures to evaluate the overall operating performance of companies in our industry, including as a means of comparing period-to-period results and as a means of evaluating our results with those of other companies.

Our non-GAAP operating loss of approximately \$616,000 and \$1.0 million for the three and six months ended September 30, 2007 respectively, declined from