

UROPLASTY INC  
Form 424B4  
December 21, 2006

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**Filed Pursuant to Rule 424(b)(4)  
Registration No. 333-138265**

**PROSPECTUS**

**2,430,000 SHARES**

**Common Stock**

We are offering up to 2,430,000 shares of common stock at \$2.00 per share.

Our common stock is traded on the American Stock Exchange under the symbol UPI. On December 20, 2006, the closing price of our common stock on the American Stock Exchange was \$2.40 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	\$ 2.00	\$ 4,860,000
Agent fees and commissions	\$ .12	\$ 291,600
Proceeds to Uroplasty before expenses	\$ 1.88	\$ 4,568,400

We have retained Craig-Hallum Capital Group LLC to act as selling agent in connection with this offering. In addition to cash commissions equal to 6% of the gross proceeds raised in this offering, the selling agent will receive warrants to purchase 5% of the shares of common stock sold in this offering. The warrants and the shares underlying the warrants are covered by this prospectus. The selling agent is not required to sell any specific number or dollar amount of securities in this offering but will use its best efforts to sell the securities offered. There are no arrangements to place any funds received in this offering in an escrow account. The offering will continue until the earlier of the sale of all shares offered by this prospectus or December 29, 2006.

**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 LLC**

Prospectus dated December 21, 2006

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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. The references in this prospectus to we, our, or us refer to Uroplasty, Inc. and its subsidiaries, unless the context indicates otherwise.*

**Overview**

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our minimally invasive products treat urinary incontinence and overactive bladder symptoms. We believe that our company is uniquely positioned because we offer a broad and diverse set of products to address the various preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. We currently offer three medical devices for the treatment of incontinence and overactive bladder symptoms.

**Market**

Voiding dysfunctions affect urinary or fecal control and can result in unwanted leakage (urinary or fecal incontinence) or uncontrolled bladder sensations (overactive bladder). 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 as \$16 billion. Overactive bladder (OAB) is a prevalent and challenging urologic problem affecting an estimated 34 million Americans. 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 provide a broad product offering of minimally invasive solutions.

**Strategy**

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

Focus on office-based solutions for physicians.

Grow our United States sales and international distribution.

Educate physicians and patients about the benefits of Urgent PC.

Provide patient-driven alternatives.

Develop, license or acquire new products.

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### **Our Products**

Macroplastique® is a minimally invasive, implantable soft tissue bulking agent for the treatment of urinary incontinence. When Macroplastique is injected into tissue around the urethra, it stabilizes and bulks tissues close to the urethra, thereby providing the surrounding muscles with increased capability to control the release of urine. Macroplastique has been sold for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from FDA pre-market approval of Macroplastique for the treatment of female stress urinary incontinence. We expect to begin marketing Macroplastique in the United States in early 2007.

I-Stop™ is a minimally invasive biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. Our I-Stop sling can correct stress urinary incontinence by providing tension-free hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine. In August 2005, FDA granted 510(k) clearance for the sale of I-Stop within the United States.

The Urgent® PC neuromodulation system is a minimally invasive device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. This product uses percutaneous tibial nerve stimulation to deliver an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. We received regulatory approvals for the sale of Urgent PC in the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we launched the product for sale in those markets. We developed a second generation Urgent PC product during 2006. Following CE mark approval and 510(k) clearance, we launched this product for sale in Europe in September 2006 and in the United States in October 2006.

### **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 recently established a sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. By expanding our United States presence, we intend to develop long-standing relationships with leading physicians treating incontinence and overactive bladder symptoms.

### **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.

Macroplastique®, Bioplastique®, PTQ™, VOX™, I-Stop™, and Urgent® PC 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:	Up to 2,430,000 shares.
Common stock outstanding before offering:	8,411,188 shares as of October 9, 2006.
Common stock to be outstanding after offering:	10,841,188 shares, assuming all of the shares offered are sold.
Use of proceeds:	We expect to use the net proceeds from this offering to fund operations 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 9, 2006 and to be outstanding after this offering exclude:

2,213,734 shares of common stock subject to outstanding options, at a weighted average exercise price of \$3.56 per share;

2,751,646 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of \$3.39 per share; and

1,027,000 shares of common stock reserved for issuance under our 2006 Stock and Incentive Plan.

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The following tables present our summary consolidated financial data for our fiscal years ended March 31, 2006 and 2005, which have been derived from our audited consolidated financial statements. The financial data for our six months ended September 30, 2006 and 2005 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.

***Consolidated Statements of Operations Data:***

	<b>Six Months Ended</b>		<b>Fiscal Year Ended March 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
	<b>September 30,</b>			
	<b>(unaudited)</b>			
Net sales	\$ 3,524,980	\$ 3,200,608	\$ 6,142,612	\$ 6,657,726
Cost of goods sold	1,008,372	883,145	1,837,716	1,755,456
Gross profit	2,516,608	2,317,463	4,304,896	4,902,270
General and administrative expenses	1,711,399	1,435,431	2,958,982	2,260,240
Research and development expenses	1,333,363	1,661,406	3,324,201	2,258,127
Selling and marketing expenses	2,536,283	1,468,639	3,399,896	2,015,655
Operating loss	(3,064,437)	(2,248,013)	(5,378,183)	(1,631,752)
Warrant benefit (expense)	(372,680)	15,423	707,320	
Interest income	37,815	54,996	142,379	30,168
Interest expense	(16,465)	(9,324)	(29,494)	(25,934)
Foreign currency exchange gain (loss)	29,964	(8,405)	(31,195)	(15,744)
Other	3,585		(413)	
Loss before income taxes	(3,382,218)	(2,195,323)	(4,589,586)	(1,643,262)
Income tax expense (benefit)	17,911	2,706	(46,873)	91,503
Net loss	\$ (3,400,129)	\$ (2,198,029)	\$ (4,542,713)	\$ (1,734,765)
Basic and diluted net loss per common share	\$ (0.46)	\$ (0.33)	\$ (0.67)	\$ (0.37)
Basic and diluted weighted average common shares	7,376,900	6,603,887	6,746,412	4,651,732

***Consolidated Balance Sheet Data:***

**March 31,**  
**2006                      2005**



**September 30,  
2006  
(unaudited)**

Cash and cash equivalents	\$ 1,983,303	\$ 1,563,433	\$ 1,405,324
Short-term investments		1,137,647	87,360
Working capital	1,941,128	2,667,053	2,374,514
Property, plant and equipment, net	1,425,102	1,079,438	1,040,253
Total assets	6,598,922	6,401,244	4,443,224
Long-term debt, less current portion	450,000	389,241	461,265
Shareholders' equity	2,561,784	3,407,050	2,791,896

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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 six fiscal years. As of September 30, 2006, we had an accumulated deficit of approximately \$14.4 million primarily as a result of costs relating to the development, including seeking regulatory approvals, and commercialization of our Macroplastique, I-Stop sling, Urgent PC neuromodulation system and related products. We expect our operating expenses relating to sales and marketing activities and product development 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, which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

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

Our future liquidity and capital requirements will depend on numerous factors including: the timing and cost involved in manufacturing scale-up and in expanding our sales, marketing and distribution capabilities in the United States markets; the cost and effectiveness of our marketing and sales efforts with respect to our existing products in international markets; the effect of competing technologies and market and regulatory developments; and the cost involved in protecting our proprietary rights. Because we have yet to achieve profitability and generate positive cash flows, we need to raise additional debt or equity financing in fiscal 2007 to continue funding for product development and continued expansion of our sales and marketing activities. There can be no guarantee that we will be successful, as we currently have no committed sources of, or other arrangements with respect to, additional equity or debt financing. We therefore cannot ensure that we will obtain additional financing on acceptable terms, or at all.

This offering is structured as a best efforts offering, whereby the selling agent is only required to use its best efforts to sell our shares and has no firm commitment or obligation to purchase any of the shares in this offering. This offering is not conditioned on the sale of a minimum dollar amount or number of shares. As a result, the amount of proceeds we raise in this offering may be substantially less than the \$12 million we need to support our current growth plans. If we are unable to raise substantial funds in this offering, we will need to rely on our existing credit facilities and curtail our product development, clinical studies and sales and marketing activities in order to conserve cash and maintain our operations through the balance of fiscal 2007. This would adversely impact our future business and prospects. In any event, because we are not profitable, we will need to raise substantial additional financing to support our operations and planned growth activities through fiscal 2008 and beyond. 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.

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

We are dependent on sales of our products that contain our Macroplastique bulking agent. Our Macroplastique product line accounted for 67% and 76%, respectively, of total net sales during fiscal 2006 and 2005. If our Macroplastique products were no longer available for sale in any key market because of regulatory, intellectual property or any other reason, our net sales from these products would significantly decline. A significant decline in our net sales could negatively impact our product development activities, our business prospects and profitability.

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

Although many of our products have received FDA approval, market acceptance is uncertain. Our failure to achieve sufficient market acceptance will significantly limit our ability to generate revenue and be profitable. Market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefits and cost-effectiveness of our products compared to products or treatment options of our competitors, and to train physicians in the proper application of our products. We cannot ensure that we will be successful in educating the marketplace about the benefits of using our products. Even if customers accept our products, this acceptance may not translate into sales if our competitors have developed similar products that our customers prefer. If our products do not achieve increasing market acceptance in the United States and internationally, our revenues will decline or we may be unable to increase our revenues and be profitable.

***Our products and facilities are subject to extensive regulation with which compliance is costly and which exposes us to penalties for non-compliance. We may not be able to obtain required regulatory approvals for our products in a cost-effective manner or at all, which could adversely affect our business and results of operations.***

The production and marketing of our products and our ongoing research and development, preclinical testing and clinical trial activities are subject to extensive regulation and review by numerous governmental authorities both in the United States and abroad. United States and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the testing, marketing and pre-market review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, exporting, labeling and record keeping procedures. We are required to obtain FDA approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot ensure that any of our products will be approved for sale. Any failure to obtain regulatory approvals or clearances could prevent us from successfully marketing our products, which could adversely affect our business and results of operations. Our failure to comply with applicable regulatory requirements could result in governmental agencies:

- imposing fines and penalties on us;
- preventing us from manufacturing or selling our products;
- bringing civil or criminal charges against us;
- delaying the introduction of our new products into the market;
- enforcing operating restrictions;
- recalling or seizing our products; or

withdrawing or denying approvals or clearances for our products.

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If any or all of the foregoing were to occur, we may not be able to meet the demands of our customers and our customers may cancel orders or purchase products from our competitors, which could adversely affect our business and results of operations.

Even if we receive regulatory approval or clearance of a product, the approval or clearance could limit the uses for which we may label and promote the product, which may limit the market for our products. Further, for a marketed product, its manufacturer and manufacturing facilities are subject to periodic reviews and inspections by FDA and foreign regulatory authorities. Subsequent discovery of problems with a product, manufacturer or facility may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market or other enforcement actions. In addition, regulatory agencies may not agree with the extent or speed of corrective actions relating to product or manufacturing problems.

If additional regulatory requirements are implemented in the foreign countries in which we sell our products, the cost of developing or selling our products may increase. In addition, we may rely on our distributors outside the United States in seeking regulatory approval to market our devices in particular countries. To the extent we do so, we are dependent on persons outside of our direct control to make regulatory submissions and secure approvals, and we do or will not have direct access to health care agencies in those markets to ensure timely regulatory approvals or prompt resolution of regulatory or compliance matters. If our distributors fail to obtain the required approvals or do not do so in a timely manner, our net sales from our international operations and our results of operations may be adversely affected.

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

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

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

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;

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

divert the attention of our management; or

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

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

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***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 United States 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 ensure that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent products or processes or otherwise gain access to our unpatented proprietary technology. We attempt to protect our trade secrets and other unpatented proprietary technology through the use of confidentiality agreements and noncompetition agreements with our current employees and with other parties to whom we have divulged trade secrets. However, these agreements may not be enforceable or may not provide meaningful protection for our proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements or in the event competitors discover or independently develop similar proprietary information.

***Product liability claims, recalls and improper use of our products could each adversely affect our business and results of operations.***

The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Our existing products were developed relatively recently and defects or risks that we have not yet identified may give rise to product liability claims. Our existing \$2 million of worldwide product liability insurance coverage may be inadequate to protect us from any liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer. Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. A recall of any of our products likely would be costly, would be uninsured and could also result in increased product liability claims. Further, while we train our physician customers on the proper usage of our products, we cannot ensure that they will implement our instructions accurately. If our products are used incorrectly by our customers, injury may result and this could give rise to product liability claims against us. Any losses that we may suffer from any liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our products, may divert management's attention from other matters and may have a negative impact on our business and our results of operations.

***If we are not able to successfully scale-up production of our products, our sales and revenues will suffer.***

In order to commercialize our products in the United States and international markets, we need to be able to produce, or subcontract the production, of our products in a cost-effective way on a large scale to meet demand, while maintaining high standards for quality and reliability. If we fail to successfully commercialize our products, we will not be profitable.

We may experience manufacturing and control problems as we begin to scale-up our future manufacturing operations, and we may not be able to scale-up manufacturing in a timely manner or at a reasonable cost to enable production in sufficient quantities. If we experience any of these problems, we may not be able to have our products manufactured and delivered in a timely manner.



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

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

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

***If we are not able to maintain sufficient quality controls, approval of our products by the European Union, FDA or other relevant authorities could be delayed or denied and our sales and revenues will suffer.***

Approval of our products could be delayed by FDA, European Union or other related authorities if our manufacturing facilities do not comply with applicable manufacturing requirements. FDA's Quality System Regulations impose elaborate testing, control, document and other quality assurance procedures. Canada and the European Union also impose requirements on quality control systems of manufacturers, which are inspected and certified on a periodic basis and may be subject to additional unannounced inspections. Failure by us or CL Medical to comply with these requirements could prevent us from obtaining FDA approval for our products and from marketing our products in the United States. We cannot ensure that our manufacturing facilities will comply with applicable requirements on a timely basis or at all.

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

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

To date, we have sold our products in foreign markets through a network of independent distributors and our direct sales force. Our ability to increase product sales in foreign markets will largely depend on our ability to develop and maintain relationships with our existing and additional distributors and to recruit, retain and motivate additional sales personnel. 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. In the United States, we have a sales organization consisting of a direct sales management group and a nationwide network of independent sales representatives and a marketing organization to market our products directly and support our distributor organizations. We anticipate continuing to expand our sales and marketing organization, as needed to support our growth. We have and will continue to incur significant continued and additional expenses to support this organization. We will need to raise additional debt or equity financing to expand our sales and marketing organizations. We may not be able to recruit, train, motivate or retain qualified sales and marketing personnel or independent sales representatives. 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.



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### ***If we are not able to acquire or license other products, our business and future growth prospects could suffer.***

As part of our growth strategy, we intend to acquire or license additional products and product candidates for development and commercialization. The success of this strategy depends upon our ability to identify, select and acquire the right products. In fact, we have an option to acquire the assets of CystoMedix, Inc., the company that has licensed the Urgent<sup>®</sup> PC technology to us.

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

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

we may be unable to integrate the acquired business successfully and realize anticipated economic, operational and other benefits in a timely manner;

the acquisition may disrupt our ongoing business, distract our management and divert our resource; and

we may not have or be able to secure adequate financing to develop or maintain the acquired business.

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

During fiscal 2006, we had two customers that individually accounted for approximately 14% and 11% of our net sales. During fiscal 2005, the same two customers individually accounted for approximately 15% and 11% of our net sales. As a result, we face the risk that one or more of our key customers may decrease its or their business with us or terminate its or their relationships with us. Any decrease in business from these customers, if we are unable to replace them, could result in a material decrease in our revenue. This could adversely affect our financial condition.

### ***Negative publicity regarding the use of silicone material in medical devices could harm our business and result in a material decrease in revenues.***

Macroplastique is comprised of medical grade, heat-vulcanized polydimethylsiloxane, which results in a solid, flexible silicone elastomer. In the early 1990 s, the United States breast implant industry became the subject of significant controversies surrounding the possible effects upon the human body of the use of silicone gel in breast implants, resulting in product liability litigation and leading to the bankruptcy of several companies, including our former parent, Bioplasty, Inc. We use only medical grade solid silicone material in our tissue bulking products and not semi-liquid silicone gel, as was used in breast implants. Negative publicity regarding the use of silicone materials in our products or in other medical devices could have a significant adverse affect on the overall acceptance of our products. We cannot ensure that the use by us and others of solid silicone in medical devices implanted in the human body will not result in negative publicity.

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

We currently derive substantially all of our net sales from 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 our FDA-approved products. 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 United States and foreign governmental trade

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regulations. Compliance with such regulations is costly and exposes us to penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

In addition, most of the countries in which we sell our products are, to some degree, subject to political, economic and 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 United States and foreign governmental controls or regulations;

the imposition of costly and lengthy new export licensing requirements;

the imposition of United States and international sanctions against a country, company, person or entity with whom we do 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;

international pricing pressure;

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 ensure 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.

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

Because our international sales are denominated primarily in euros, currency fluctuations in countries where we do business may render our products less price competitive than those of competing companies whose sales are denominated in weaker currencies. We report our financial results in U.S. dollars, and fluctuations in the value of either the dollar or the currencies in which we transact business can have a negative impact on our results of operations and financial condition. Consequently, we have exposure to foreign currency exchange risks. We do not hedge any of our foreign currency risk.

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

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

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

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

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

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

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

Our success depends on the availability of reimbursement for the cost of our products from third-party payors, such as government health authorities, private health insurance plans and managed care organizations. There is no uniform policy for reimbursement in the United States and foreign countries. We believe that the ease of obtaining, and the amount of, reimbursement for urinary incontinence treatment has a significant impact on the decisions of health care providers regarding treatment methods and products. Accordingly, changes in the extent of coverage or a reduction in

reimbursement rates under any or all third-party reimbursement programs may cause a decline in purchases of our products, which would materially adversely



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affect the market for our products. Alternatively, we might respond to reduced reimbursement rates by reducing the prices of our products, which could also reduce our revenues.

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

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

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

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

***Proposals to modify the health care system in the United States 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 United States 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

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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 business strategies. Also, we depend on the continued service of key managerial, scientific, sales and technical personnel, as well as our ability to continue to attract and retain additional highly qualified personnel. We compete for such personnel with other companies, academic institutions, government entities and other organizations. Any loss or interruption of the services of our other key personnel could also significantly reduce our ability to effectively manage our operations and grow our business because we cannot ensure that we would be able to find an appropriate replacement should the need arise.

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

### **Risks Relating to this Offering**

***Your investment is immediately at risk.***

This is a best efforts offering with no minimum number or dollar amount of securities that must be sold. As a result, any funds received from investors in this offering will be available to us regardless of the number of shares sold in this offering. Therefore, your investment is immediately at risk.

***We will retain broad discretion in the allocation of the net proceeds of this offering and may not allocate the proceeds in the most profitable manner.***

Our management will have broad discretion in determining the specific timing and uses of the offering proceeds. We have not made a specific allocation for the uses of the net proceeds. Accordingly, investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

***You may be unable to sell your investment.***

There is only a limited trading market for our common stock, which is traded 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 United States or international reimbursement systems;

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changes in accounting standards, policies, guidance or interpretations;

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

general economic conditions.

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

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

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

In August 2006, we completed a private placement in which we sold 1,389,999 shares of our common stock at \$1.50 per share. In April 2005, we completed a private placement in which we sold 2,147,142 shares of our common stock at \$3.50 per share. All of these shares have been registered for resale under the Securities Act and are freely tradeable.

The following securities that may be exercised into shares of our common stock were issued and outstanding as of October 9, 2006:

stock options to purchase 2,213,734 shares of our common stock at a weighted average exercise price of \$3.56 per share; and

warrants to purchase 2,751,646 shares of our common stock at a weighted average exercise price of \$3.39 per share.

Further, if we exercise our option to acquire the assets of CystoMedix, we will need to issue our common stock to CystoMedix for the purchase price.

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

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. We will be evaluating our internal controls systems to allow management to report on, and our independent auditors to attest to, our internal controls. We will be performing the system and process evaluation and testing (and any necessary remediation) required to comply with the management certification and auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 by our March 31, 2008 deadline, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. 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.

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***Changes in accounting standards regarding stock option plans could limit the desirability of granting stock options, which could harm our ability to attract and retain employees, and would also negatively impact our results of operations.***

The Financial Accounting Standards Board has issued Statement No. 123(R), *Share-Based Payments*, SFAS 123(R), which requires all companies to treat the fair value of stock options granted to employees as an expense, beginning in the first fiscal year that begins after December 15, 2005, for small business issuers. Accordingly, SFAS 123(R) became effective for us beginning April 1, 2006. For our fiscal 2006 and prior years, we generally have not recorded compensation expense in connection with stock option grants to employees. Because we are now required to expense the fair value of employee stock option grants, granting stock options is less attractive because of the additional expense recognized associated with these grants, which will negatively impact our results of operations. If we had adopted the fair value method for fiscal 2006 and 2005, our net loss for the respective fiscal years would have been \$3,062,324, and \$2,321,745 higher than reported and net loss per share would have increased by \$0.46, and \$0.50 per common share, respectively. Nevertheless, stock options are an important employee recruitment and retention tool, and we may not be able to attract and retain key personnel if we reduce the scope of our employee stock option program.

In February 2006, our board of directors approved a plan to accelerate, effective February 2, 2006, the vesting of out-of-the-money, unvested stock options previously granted to our employees, officers and directors. An option was considered out-of-the-money if the stated exercise price exceeded \$2.85, the then closing price of our common stock. Pursuant to this action, options to purchase approximately 400,000 shares of our common stock with a weighted average exercise price of \$4.49 per share became exercisable immediately.

We accelerated the vesting of these options to minimize the amount of compensation expense we must recognize upon adoption of SFAS No. 123(R). None of these options had intrinsic value at the acceleration date under APB 25. We expect that the acceleration of the vesting of these options reduced the pre-tax stock option expense by approximately \$1.4 million, in the aggregate, calculated using the Black-Scholes option valuation model, that we would have otherwise recognized over the next three fiscal years, upon adoption of SFAS No. 123(R). We have included the charge attributed to the accelerated vesting of the options in the pro forma disclosures to our consolidated financial statements for the fiscal year ended March 31, 2006. However, certain outstanding options, with a cashless exercise provision, and certain outstanding options classified as liabilities, could result in a significant charge to compensation expense in future periods, as we will mark those options to fair value at each reporting period until settlement. Also, additional options as granted to attract or retain new employees could result in significant charge to compensation expense.

***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 shareholders may consider favorable. For example, our articles of incorporation authorize our board of directors to issue up to 40 million shares of stock which, without shareholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights. With these rights, the holders of such shares could make it more difficult for a third party to acquire us. In addition, our articles of incorporation provides for a staggered board of directors, whereby directors serve for three year terms, with approximately one third of the directors coming up for reelection each year. Having a staggered board will make it more difficult for a third party to obtain control of our board of directors through a proxy contest, which may be a necessary step in an acquisition of us that is not favored by our board of directors.

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



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voting stock or an affiliate of ours that owned 10% or more of our outstanding voting stock during the past four years, subject to certain exceptions.

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

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

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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,

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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 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 \$4.4 million, assuming all of the shares being offered are sold at \$2.00 per share, after deducting estimated agent commissions and offering expenses of approximately \$441,600. Because this is a best efforts offering, there is no guarantee that all of the shares will be sold.

We intend to use the net proceeds from this offering to fund operations 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.

**PRICE RANGE OF COMMON STOCK**

Effective October 3, 2005, our common stock became listed on the American Stock Exchange under the symbol UPI. On December 20, 2006, the closing price of our common stock on the American Stock Exchange was \$2.40 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 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 20, 2006	\$ 2.40	\$ 3.40
<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



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<b>Fiscal Year 2005</b>	<b>Low</b>	<b>High</b>
April 1 - June 30, 2004	\$ 2.60	\$ 5.25
July 1 - September 30, 2004	2.90	4.60
October 1 - December 31, 2004	4.10	6.30
January 1 - March 31, 2005	3.15	5.50

As of October 9, 2006, we had approximately 534 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, 2006 and 2005, which has been derived from our audited consolidated financial statements. The financial data for our six months ended September 30, 2006 and 2005 has been derived from our unaudited consolidated financial statements which, in management's opinion, have been prepared on the same basis as our 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.

***Consolidated Statements of Operations Data:***

	<b>Six Months Ended</b>		<b>Fiscal Year Ended March 31,</b>	
	<b>September 30,</b>		<b>2006</b>	<b>2005</b>
	<b>2006</b>	<b>2005</b>		
	<b>(Unaudited)</b>			
Net sales	\$ 3,524,980	\$ 3,200,608	\$ 6,142,612	\$ 6,657,726
Cost of goods sold	1,008,372	883,145	1,837,716	1,755,456
Gross profit	2,516,608	2,317,463	4,304,896	4,902,270
General and administrative expenses	1,711,399	1,435,431	2,958,982	2,260,240
Research and development expenses	1,333,363	1,661,406	3,324,201	2,258,127
Selling and marketing expenses	2,536,283	1,468,639	3,399,896	2,015,655
Operating loss	(3,064,437)	(2,248,013)	(5,378,183)	(1,631,752)
Warrant benefit (expense)	(372,680)	15,423	707,320	
Interest income	37,815	54,996	142,379	30,168
Interest expense	(16,465)	(9,324)	(29,494)	(25,934)
Foreign currency exchange gain (loss)	29,964	(8,405)	(31,195)	(15,744)
Other	3,585		(413)	
Loss before income taxes	(3,382,218)	(2,195,323)	(4,589,586)	(1,643,262)
Income tax expense (benefit)	17,911	2,706	(46,873)	91,503
Net loss	\$ (3,400,129)	\$ (2,198,029)	\$ (4,542,713)	\$ (1,734,765)
Basic and diluted net loss per common share	\$ (0.46)	\$ (0.33)	\$ (0.67)	\$ (0.37)
Basic and diluted weighted average common shares	7,376,900	6,603,887	6,746,412	4,651,732

***Consolidated Balance Sheet Data:***

	<b>September 30, 2006 (Unaudited)</b>	<b>March 31,</b>	
		<b>2006</b>	<b>2005</b>
Cash and cash equivalents	\$ 1,983,303	\$ 1,563,433	\$ 1,405,324
Short-term investments		1,137,647	87,360
Working capital	1,941,128	2,667,053	2,374,514
Property, plant and equipment, net	1,425,102	1,079,438	1,040,253
Total assets	6,598,922	6,401,244	4,443,224
Long-term debt, less current portion	450,000	389,241	461,265
Shareholders' equity	2,561,784	3,407,050	2,791,896



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

**Strategy**

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

Focus on office-based solutions for physicians.

Grow our United States sales and international distribution.

Educate physicians and patients about the benefits of Urgent PC.

Provide patient-driven alternatives.

Develop, license or acquire new products.

**Our Products**

Macroplastique is a minimally invasive, implantable soft tissue bulking agent for the treatment of urinary incontinence. When Macroplastique is injected into tissue around the urethra, it stabilizes and bulks tissues close to the urethra, thereby providing the surrounding muscles with increased capability to control the release of urine. Macroplastique has been sold for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from FDA pre-market approval of Macroplastique for the treatment of female stress urinary incontinence. We expect to begin marketing Macroplastique in the United States in early 2007. Following market introduction, we will conduct customary, FDA-required post-approval studies to obtain market feedback on safety and effectiveness of the product. We cannot ensure that we can market the product profitably.

I-Stop is a minimally invasive biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. Our I-Stop sling can correct stress urinary incontinence by providing tension-free hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine. In August 2005, FDA granted 510(k) clearance for the sale of I-Stop within the United States.

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

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the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we launched the product for sale in those markets. We developed a second generation Urgent PC product during 2006. Following CE mark approval and 510(k) clearance, we launched this product for sale in Europe in September 2006 and in the United States in October 2006.

## **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 recently established a sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. By expanding our United States presence, we intend to develop long-standing relationships with leading physicians treating incontinence and overactive bladder symptoms.

## **Critical Accounting Policies**

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

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*Foreign Currency Translation/Transactions.* The financial statements of our foreign subsidiaries were translated in accordance with the provisions of SFAS No. 52 Foreign Currency Translation. Under this Statement, we translate all assets and liabilities using period-end exchange rates, and we translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders' equity. We recognize foreign currency transaction gains and losses in the statement of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates, resulting in an increase in the volatility of our consolidated statements of operations. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders' equity.

*Impairment of Long-Lived Assets.* Long-lived assets at September 30, 2006 consist of property, plant and equipment and intangible assets. We review our long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. We measure the recoverability of assets to be held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If we consider such assets impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We report assets to be disposed of at the lower of the carrying amount or fair value less costs to sell.

*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. We must measure that cost 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) is a replacement of Statement No. 123, *Accounting for Stock-Based Compensation*, and supersedes APB 25, and its related interpretive guidance.

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. FAS 123(R) permits us to use any option-pricing model that meets the fair value objective in the Statement. We adopted FAS 123(R) for the first time in the first quarter of fiscal year 2007. FAS 123(R) allows two methods for determining the effects of the transition: the modified prospective and the modified retrospective. We have adopted the modified prospective transition method beginning April 1, 2006. We calculated the pro forma compensation costs presented previously and in our prior filings using a Black-Scholes option pricing model. These compensation costs may not be indicative of amounts which we will incur in future years.

*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, 2006, we generated approximately \$15,423,000 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 a portion of the deferred tax asset. 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.

In addition, U.S. tax rules impose limitations on the use of net operating loss following certain changes in ownership. Such a change in ownership may limit the amount of these benefits that would be available to offset future taxable income each year, starting with the year of ownership change.



**Table of Contents****Results of Operations****Six Months Ended September 30, 2006 Compared to Six Months Ended September 30, 2005**

*Net Sales.* During the six months ended September 30, 2006, net sales were \$3.5 million, representing a \$324,000 or a 10% increase when compared to net sales of \$3.2 million for the six months ended September 30, 2005. Excluding the impact of fluctuations in foreign currency exchange rates, sales increased by approximately 7%. An 11% decline in sales of Macroplastique products was more than offset by sales of the Urgent PC and an increase in sales of the I-Stop. In the six months ended September 30, 2005, we had no sales of the Urgent PC and had minimal sales of the I-Stop.

We attribute the decline in sales of the Macroplastique products primarily to adverse changes in the implementation of reimbursement policies by the governments in countries outside the United States, and the increase in pricing competition. We expect this to adversely impact our future sales in those markets. In response, we have implemented targeted volume price reductions, have increased the number of training workshops targeted to our distributors and key incontinence surgeons, and are sponsoring scientific podium presentations and seminars at the most highly recognized international incontinence congresses. We cannot ensure that these initiatives will increase Macroplastique sales.

*Gross Profit.* Gross profit was \$2.5 million and \$2.3 million for the six months ended September 30, 2006 and 2005, respectively, or 71% and 72% of net sales in the respective periods. We attribute the decline in gross profit percent to lower manufacturing capacity utilization in the first fiscal quarter from the decline in Macroplastique sales and duplicate manufacturing facilities in the United States, offset partially by increased manufacturing capacity utilization in the second fiscal quarter. We stepped up production in the second quarter to build inventory to meet our needs during the transition period when we relocate our manufacturing operations to our new corporate headquarters in Minnetonka, MN. We expect to relocate the manufacturing operations in our third fiscal quarter and anticipate FDA qualification of our new manufacturing operations in early 2007.

*General and Administrative Expenses (G&A).* G&A expenses increased from \$1.4 million during the six months ended September 30, 2005 to \$1.7 million during the same period in 2006. Included in the 2006 period is a \$392,000 non-cash, SFAS 123(R) charge for share-based employee compensation. Excluding this charge, G&A expenses declined by \$116,000 because of decreased personnel-related costs offset by increased rent expense and because during the six months ended September 2005, we incurred certain charges related to the installation of our new information system and AMEX listing fees, offset by a \$145,000 reversal of bad debt expense.

*Research and Development Expenses (R&D).* R&D expenses decreased from \$1.7 million during the six months ended September 30, 2005 to \$1.3 million during the same period in 2006. Included in the 2006 period is a \$17,000 non-cash, SFAS 123(R) charge for share-based employee compensation. We attribute the decrease to decreased personnel-related costs of \$213,000 and consulting expense of \$126,000, offset by increased clinical costs of \$125,000 for an ongoing clinical study for our PTQ product and for a study we launched during the three months ended September 30, 2006 to compare the efficacy of the Urgent PC against a leading drug therapy for treatment of overactive bladder symptoms. During the six months ended September 30, 2005 we incurred consulting expense primarily for the development of our second generation Urgent PC product and a \$205,000 expense related to severance compensation for our former Vice President of Research and Development and Managing Director of our United Kingdom subsidiary.

*Selling and Marketing Expenses (S&M).* S&M expenses increased from \$1.5 million during the six months ended September 30, 2005 to \$2.5 million during the same period in 2006. Included in the 2006 period is a \$37,000 non-cash, SFAS 123(R) charge for share-based employee compensation. We attribute the increase to the \$571,000 increase in compensation-related costs, primarily for our U.S. direct sales force and marketing organization, the

\$176,000 increase in travel-related costs and an increase in other costs to support our expanded organization and marketing activities.

*Other Income (Expense).* Other income (expense) includes interest income, interest expense, warrant expense or benefit, foreign currency exchange gains and losses and other non-operating costs when incurred.



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Our financial results are subject to material fluctuations based on changes in currency exchange rates. Other income (expense) was \$(318,000) and \$53,000 for the six months ended September 30, 2006 and 2005, respectively.

As a result of the suspension of the exercise of the 706,218 warrants we originally issued in July 2002, we granted a like number of new common stock purchase warrants to the holders of the expired warrants in April 2005. The new warrants will be exercisable at \$2.00 per share for 90 days after the effective date of a registration statement covering the shares underlying these warrants. Although as of September 30, 2006, we had filed this registration statement, the U.S. Securities and Exchange Commission had not declared it effective. We anticipate seeking effectiveness of the registration statement before the end of calendar year 2006. In April 2005, we recognized a liability and a charge to equity of approximately \$1.4 million associated with the grant of these new warrants. We determined the fair value of these warrants using the Black-Scholes option-pricing model. We have since reduced the reported liability by approximately \$362,000 due to the decrease in the fair value of these warrants from their date of issuance through September 30, 2006. We recorded a warrant expense of \$373,000 for the six months ended September 30, 2006 and a warrant benefit of \$15,000 for the six months ended September 30, 2005. We will continue to remeasure the value of this liability in relation to its fair value and adjust accordingly until such time as the warrants are exercised or expire.

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 \$30,000 and \$(8,000) for the six months ended September 30, 2006 and 2005, respectively.

*Income Tax Expense.* Our Dutch subsidiaries recorded income tax expense of \$18,000 and \$3,000 for the six months ended September 30, 2006 and 2005, respectively. For fiscal 2007, the Dutch income tax rate is 25.5% for 22,689 (approximately \$29,000) of profit and 29.6% for amounts above 22,689 compared to 27% and 31.5% in fiscal 2006, respectively.

*Non-GAAP Financial Measures.* In addition to disclosing the financial results for the six months ended September 2006 calculated in accordance with U.S. generally accepted accounting principles (GAAP), our discussion of the results of operations above contains non-GAAP financial measures that exclude the effects of share-based employee compensation under the requirements of FAS 123(R). The non-GAAP financial measures used by management and disclosed by us exclude the income statement effects of share-based employee compensation under the requirements of FAS 123(R). The non-GAAP financial measures disclosed by us should not be considered a substitute for, or superior to, financial measures calculated in accordance with GAAP, and the consolidated financial results calculated in accordance with GAAP and reconciliations to those financial statements should be carefully evaluated. 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.

Because we excluded FAS 123(R) share-based employee compensation expense in some of our discussion above, these financial measures are treated as a non-GAAP financial measure under Securities and Exchange Commission rules. Management uses non-GAAP financial measures for internal managerial purposes, including as a means to compare period-to-period results on a consolidated basis and as a means to evaluate our results on a consolidated basis compared to those of other companies.

We disclose this information to the public to enable investors who wish to more easily assess our performance on the same basis applied by management and to ease comparison on both a GAAP and non-GAAP basis among peer companies.



**Table of Contents****Years Ended March 31, 2006 Compared to Year Ended March 31, 2005**

*Net Sales.* In fiscal 2006, net sales of all products were \$6.1 million, representing an 8% decrease when compared to net sales of \$6.7 million for fiscal 2005. Excluding fluctuations in foreign currency exchange rates, we had a sales decrease of approximately 5% primarily due to a \$810,000 decline in sales of our Macroplastique products offset by a \$506,000 net increase in all of our other products. We attribute this decline primarily to adverse changes in reimbursement policies of the insurers and the increase in pricing competition. We expect these reimbursement changes and the increase in price competition to adversely impact our future sales in those markets. In these markets we have launched a strategy to increase sales of our existing products, and to expand our platform of products for the treatment of voiding dysfunctions. We are conducting training workshops targeted to our sales personnel, distributors and key incontinence surgeons, and we are sponsoring scientific podium presentations and seminars at key international incontinence congresses. We are also seeking to broaden our patient base to include Urgent PC treatment for symptoms of overactive bladder (OAB), the I-Stop sling procedure for treatment of female stress urinary incontinence (SUI) and hypermobility and PTQ Implants and Urgent PC treatments for fecal incontinence. We cannot ensure that these initiatives will increase sales.

*Gross Profit.* Gross profit was \$4.3 million and \$4.9 million for the fiscal years ended March 31, 2006 and 2005, respectively, or 70% and 74% of net sales. The decline in gross profit percent is attributed primarily to the decline in sales of the above-average gross margin Macroplastique product, and certain one-time costs related to updating our manufacturing quality systems. Gross profit as a percentage of net sales between periods fluctuates based on the following factors: our unit sales, our utilization of manufacturing capacity, the mix of products sold with different gross margins, the mix of customers (and different discounts to them), the mix of direct sales versus sales through distributors (with higher margins on direct sales), and currency fluctuations. Historically, our gross margin has ranged from approximately 70-80% of net sales.

*General and Administrative Expenses (G&A).* G&A expenses increased from \$2.3 million during fiscal 2005 to \$3.0 million during fiscal 2006. The increase in expense is attributed to: \$590,000 increase in salary costs, including \$150,000 for severance pay and \$100,000 option expense for former executives, \$170,000 increase in information ( IT ) expense, \$100,000 increase in legal and accounting fees, \$80,000 increase in recruiting costs, \$50,000 of expenses related to our listing on the American Stock Exchange, \$110,000 increase in depreciation and amortization expense, general price increases and fluctuations in foreign currency exchange rates, offset by a decrease in bad debt expense of \$330,000. The IT consulting expense relates to the implementation of a new computer software system, including training and post-implementation support.

*Research and Development Expenses (R&D).* R&D expenses increased 47% from \$2.3 million during fiscal 2005 to \$3.3 million during fiscal 2006. The increase in expense is attributed to a \$350,000 increase in salary costs, including \$170,000 for severance pay to a former executive, and \$770,000 for consulting expense for product development and regulatory approvals, offset by a \$130,000 reduction in costs for clinical trials and testing.

*Selling and Marketing Expenses (S&M).* S&M expenses increased 69% from \$2.0 million during fiscal 2005 to \$3.4 million during fiscal 2006. The increase in expenses is attributed to \$940,000 for expansion of our direct sales force and marketing organizations in the United States, \$190,000 for increase in costs for travel, trade-shows and conventions, \$90,000 for increase in consulting expense, and general price increases and fluctuations in foreign currency exchange rates.

*Other Income (Expense).* Other income (expense) includes interest income, interest expense, warrant expense or benefit, foreign currency exchange gains and losses and other non-operating costs when incurred. Our financial results are subject to material fluctuations based on changes in currency exchange rates. Other income (expense) was \$788,597 and \$(11,510) for fiscal 2006 and fiscal 2005, respectively.

In July 2002, we conducted a rights offering pursuant to which our stockholders purchased certain units consisting of shares of our common stock and common stock purchase warrants exercisable for two years at \$2.00 per share. However, we suspended the exercise of the warrants when we delayed the filing of our annual report on Form 10-KSB for the fiscal year ended March 31, 2004. As a result, 706,218 of the warrants lapsed

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unexercised at July 31, 2004. In April 2005, we granted a like number of new common stock purchase warrants to the holders of the expired warrants. The new warrants will be exercisable at \$2.00 per share for 90 days after the effective date of a new registration statement covering the resale of the shares underlying these warrants. We have filed a registration statement covering such warrants on Form SB-2 with the Securities and Exchange Commission (SEC). In April 2005, we recognized a liability and equity charge of \$1.4 million associated with the grant of these warrants. A net warrant benefit of \$707,320 for fiscal 2006 is included in the statement of operations which represents the change in the fair value of the warrants since their issuance due to the change in value of the common stock which may be acquired by the exercise of these warrants.

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 losses of \$31,195 and \$15,744 for fiscal 2006 and fiscal 2005, respectively.

*Income Tax Expense (Benefit).* Our Dutch subsidiaries recorded income tax expense (benefit) of \$(46,873) and \$91,503 for fiscal 2006 and fiscal 2005, respectively. We cannot use the U.S. net operating loss carry forwards to offset taxable income in foreign jurisdictions. For fiscal 2006, the Dutch income tax rate was 25.5% for 22,689 (approximately \$27,500) of profit and 29.6% for amounts above 22,689 compared to 27% and 31.5% in fiscal 2005, respectively.

**Liquidity and Capital Resources**

*Cash Flows.* As of September 30, 2006, our cash and cash equivalents balances totaled \$2.0 million.

At September 30, 2006, we had working capital of approximately \$1.9 million. For the six months ended September 2006, we used \$2.4 million of cash in operating activities, compared to \$1.8 million of cash used in the same period a year ago. We attribute the increase in the use of cash for operating activities primarily to the increase in our net loss and investment in working capital.

*Sources of Liquidity.* In April 2005, we conducted a private placement in which we sold 2,147,142 shares of our common stock at a price per share of \$3.50, together with warrants to purchase 1,180,928 shares of our common stock, for an aggregate purchase price of approximately \$7.5 million. The stock sale proceeds were offset by costs of approximately \$935,000, resulting in net proceeds of approximately \$6.6 million. The warrants are exercisable for five years at an exercise price of \$4.75 per share.

In October 2006, we amended our business loan agreement with Venture Bank. The amended agreement provides for a credit line of up to \$500,000 secured by our assets and will expire in April 2007 if not renewed. We may borrow up to 50% of the value of the inventory on hand in the U.S. and 75% of the U.S. accounts receivable value. The bank charges interest on the loan at the rate of 1 percentage point over the prime rate (8.25% on September 30, 2006), subject to a minimum interest rate of 7% per annum. In addition, Uroplasty BV, one of our subsidiaries entered into an arrangement with Rabobank of The Netherlands for a 200,000 (approximately \$258,500) credit line. At September 30, 2006, we had no borrowings under any of our credit lines.

In August 2006, we entered into a securities purchase agreement with certain investors pursuant to which we sold approximately 1.4 million shares of our common stock for \$1.50 per share, together with warrants to purchase 695,000 shares of our common stock, for aggregate proceeds of approximately \$2.1 million. After offset for our estimated costs of \$183,000, we received net proceeds of \$1.9 million. The warrants are exercisable for five years (but commencing 181 days after closing) at an exercise price of \$2.50 per share.

In May 2006, we also entered into a \$100,000 3-year, term loan agreement with Venture Bank at an interest rate of 8.25% per annum. We used these proceeds for certain capital expenditures relating to the relocation of our facility to our Minnetonka, Minnesota location.

Because we have yet to achieve profitability and generate positive cash flows, we need to raise additional debt or equity financing in fiscal 2007 to continue funding our product development and continued expansion

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of our sales and marketing activities. There can be no guarantee that we will be successful, as we currently have no committed sources of, or other arrangements with respect to, additional equity or debt financing. We therefore cannot ensure that we will obtain additional financing on acceptable terms, or at all. If we are unable to raise substantial funds in fiscal 2007, we will need to rely on our existing credit facilities and curtail our operations including product development, clinical studies and sales and marketing activities in order to conserve cash and maintain our operations through the balance of fiscal 2007. This would adversely impact our future business and prospects. In any event, because we are not profitable, we will need to raise substantial additional financing to support our operations and planned growth activities in fiscal 2008 and beyond. Ultimately, we will need to achieve profitability and generate positive cash flows from operations to fund our operations and grow our business.

For the balance of fiscal 2007, we expect to incur significant research and development expenses, including those in connection with clinical trials for the Urgent PC. We also expect that during the balance of fiscal 2007, we will continue to incur significant expenses as we fund our selling and marketing organization in the United States to market our products.

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix for the Urgent PC product. The agreement required us to pay CystoMedix an initial payment of \$225,000 and an additional payment of \$250,000 in 12 monthly installments of \$20,833, with the last payment made in the first quarter of fiscal 2007. We capitalized the aggregate amount as licensed technology and are amortizing it over the term of the agreement. We will also pay CystoMedix a 7% royalty on product sales. However, the 7% royalty is first offset against the monthly royalty installments. Currently we do not project making any additional royalty payments to CystoMedix in fiscal 2007.

CystoMedix has also granted us an exclusive option to acquire its assets. The purchase price is \$3,485,000, reduced by up to \$50,000 of liabilities assumed by us. However, the \$3,485,000 amount used to compute the purchase price will increase at a rate of 10% per year after April 2007, if the option is not exercised earlier. The purchase price is payable in shares of our common stock valued at the average of the closing bid price of our shares for the 20 trading days prior to our exercise of the option. We may exercise the option until June 2008. If we exercise the option, we will also assume up to \$1.4 million of bridge loan advances made to CystoMedix by its Chairman. We would repay up to \$1.1 million of the bridge loan advances at closing and would issue our common stock for the balance of the bridge loan based on the above option price. We also have certain rights of first refusal to acquire CystoMedix's assets in the event CystoMedix receives a third party offer in advance of any exercise of our option. We will need to raise additional equity or debt funds in order to consummate the CystoMedix acquisition, should we elect to do so.

We have two exclusive distribution agreements with CL Medical allowing us to market and sell the I-Stop urethral sling: effective February 2006, a six-year agreement, with a right to renew it for successive five-year terms, for distribution in the United States and, effective May 2005, a one-year agreement with automatic renewal for up to two years, for distribution in the United Kingdom. Under the agreements, we are required to purchase a minimum of \$527,000 of units in the first 12-month period following January 1, 2006, increasing to \$2.7 million of units in the fifth year of the agreement, for an aggregate commitment of approximately \$6.9 million of units over the five-year period, subject to periodic adjustment based on the value of the euro.

We were obligated to pay royalties of 5% of net sales of Macroplastique products in the U.S. with a minimum of \$50,000 per year. This royalty agreement expired on May 1, 2006. Under another royalty agreement we pay royalties, in the aggregate, of three to five percent of net sales of Macroplastique, Bioplastique, and PTQ Implants subject to a monthly minimum of \$4,500. The royalties payable under this agreement will continue until the patent referenced in the agreement expires in 2010. Under a license agreement for the Macroplastique Implantation System, we pay a royalty of 10 British pounds for each unit sold during the life of the patent.

We have a pension plan covering 14 employees in The Netherlands, reported as a defined benefit plan. We pay premiums to an insurance company to fund annuities for these employees. However, we are responsible for funding additional annuities based on continued service and future salary increases. We closed this defined benefit plan for new employees in April 2005. As of that date, the Dutch subsidiary established a



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defined contribution plan that now covers new employees. We also closed our UK subsidiary's defined benefit plan to further accrual for all employees effective December 31, 2004. In March 2005, the UK subsidiary established a defined contribution plan that now covers new employees. As of September 30, 2006, we had an accrued pension liability of \$642,000.

In January 2006, we entered into a long-term lease with Liberty Property Limited Partnership for an 18,258 square foot facility for our U.S. headquarters located at 5420 Feltri Road, Minnetonka, Minnesota. The lease effective date was May 1, 2006, has a term of 96 months, requires average annual minimum rent payments of approximately \$140,000 and requires payments for operating expenses estimated to be approximately \$82,000 in the first 12 months.

Repayments of our contractual obligations as of September 30, 2006, consisting of royalties, notes payable (inclusive of interest), and operating leases, are summarized below:

	Total	Payments Due by Period			
		Remainder of Fiscal 2007	Fiscal 2008 and 2009	Fiscal 2010 and 2011	Fiscal 2012 and Thereafter
Minimum royalty payments	\$ 220,500	\$ 27,000	\$ 108,000	\$ 85,500	\$
Minimum purchase agreements	6,601,542	377,587	2,112,719	4,111,236	
Notes payable, including interest	672,860	86,363	192,522	107,045	286,930
Operating lease commitments	1,453,844	128,535	471,504	366,330	487,475
Total contractual obligations	\$ 8,948,746	\$ 619,485	\$ 2,884,745	\$ 4,670,111	\$ 774,405

**Recent Accounting Pronouncements**

In September 2006, FASB issued Statement No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans*, or SFAS 158, which requires employers to recognize the overfunded or underfunded status of a defined benefit postretirement plan as an asset or liability in its financial statements and to recognize changes in that funded status in the year in which the changes occur. The effective date would be for any full fiscal years ending after December 15, 2006. We are currently evaluating the impact, if any, of adopting SFAS 158 on our financial statements.

In September 2006, FASB issued Statement No. 157, *Fair Value Measurements*, or SFAS 157, which defines fair value and establishes a framework for measuring fair value in generally accepted accounting principles. More precisely, SFAS 157 sets forth a standard definition of fair value as it applies to assets or liabilities, the principal market (or most advantageous market) for determining fair value (price), the market participants, inputs and the application of the derived fair value to those assets and liabilities. The effective date of this pronouncement is for all full fiscal and interim periods beginning after November 15, 2007. We are currently evaluating the impact, if any, of adopting SFAS 157 on our financial statements.

In July 2006, FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes - an Interpretation of FASB Statement 109*, or FIN 48, which clarifies the accounting for uncertainty in tax positions. FIN 48 provides that the tax effects from an uncertain tax position can be recognized in financial statements, only if the position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective as of the beginning of our 2008 fiscal year, with the cumulative effect of the change in accounting principle recorded as an adjustment to opening retained earnings. We are currently evaluating the

impact, if any, of adopting FIN 48 on our financial statements.

In May 2005, FASB issued Statement No. 154, *Accounting Changes and Error Corrections*, or SFAS 154, which requires retrospective application of a voluntary change in accounting principle with all prior period financial statements presented using the new accounting principle, unless it is impracticable to do so. SFAS 154 also requires accounting for a change in method of depreciating or amortizing a long-lived nonfinancial asset prospectively as a change in estimate (prospectively) affected by a change in accounting principle. Further, SFAS 154 requires that corrections of errors in previously issued financial statements be termed a restatement. The new standard is effective for accounting changes and correction of errors made in fiscal years

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beginning after December 15, 2005. Early adoption of this standard is permitted for accounting changes and correction of errors made in fiscal years beginning after June 1, 2005. We do not believe the adoption of SFAS 154 will have a material effect on our financial position or results of operations.

In March 2005, FASB issued FASB Interpretation No. 47, or FIN 47, which clarifies when an entity has sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 was effective for us in our 2006 fiscal year. Adoption of FIN 47 did not have a material impact on our consolidated financial statements.

In December 2004, FASB issued SFAS No. 123(R), *Share-Based Payment*, which requires all share-based payments to employees, including grants of employee stock options, to be valued at fair value on the date of grant, and to be expensed over the applicable vesting period. SFAS 123(R) was effective for us beginning on April 1, 2006. Please refer to the discussion in Critical Accounting Policies Stock Based Compensation and Accelerated Vesting.

In November 2004, FASB issued SFAS No. 151, *Inventory Costs, An Amendment of Accounting Research Bulletin No. 43, Chapter 4*, which requires us to treat abnormal freight, handling costs and wasted materials (spoilage) as current period charges rather than as a portion of inventory cost. Additionally, the standard clarifies that we should allocate fixed production overhead based on the normal capacity of a production facility. The statement is effective for us beginning in our 2007 fiscal year. Adoption of SFAS No. 151 did not have a material impact on our consolidated financial statements.

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**BUSINESS**

**Overview**

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Our minimally invasive products treat urinary incontinence and overactive bladder symptoms. We believe that our company is uniquely positioned because we offer a broad and diverse set of products to address the various preferences of doctors and patients, as well as the quality of life issues presented by voiding dysfunctions. We currently offer three medical devices for the treatment of incontinence and overactive bladder symptoms.

Macroplastique is a minimally invasive, implantable soft tissue bulking agent for the treatment of urinary incontinence. When Macroplastique is injected into tissue around the urethra, it stabilizes and bulks tissues close to the urethra, thereby providing the surrounding muscles with increased capability to control the release of urine. Macroplastique has been sold for urological indications in over 40 countries outside the United States since 1991. In October 2006, we received from FDA pre-market approval of Macroplastique for the treatment of female stress urinary incontinence. We expect to begin marketing Macroplastique in the United States in early 2007.

I-Stop is a minimally invasive biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. Our I-Stop sling can correct stress urinary incontinence by providing tension-free hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine. In August 2005, FDA granted 510(k) clearance for the sale of I-Stop within the United States.

The Urgent PC neuromodulation system is a minimally invasive device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. This product uses percutaneous tibial nerve stimulation to deliver an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. We received regulatory approvals for sale of Urgent PC in the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we launched the product for sale in those markets. We developed a second generation Urgent PC product during 2006. Following CE mark approval and 510(k) clearance, we launched this product for sale in Europe in September 2006 and in the United States in October 2006.

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 recently established a sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. By expanding our United States presence, we intend to develop long-standing relationships with leading physicians treating incontinence and overactive bladder symptoms.

**Market**

Voiding dysfunctions affect urinary or fecal control and can result in unwanted leakage (urinary or fecal incontinence) or uncontrolled bladder sensations (overactive bladder). 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 as \$16 billion. Overactive bladder (OAB) is a prevalent and challenging urologic problem affecting an

estimated 34 million Americans. 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

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minimally invasive treatment first. We believe that our company is uniquely positioned because we provide a broad product offering of minimally invasive solutions.

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

*Aging population.* The number of individuals developing voiding dysfunctions will increase significantly as the population ages and as life expectancies continue to rise.

*Technology advances and patient awareness.* Patients often weigh the clinical benefits against the invasiveness of the procedures when choosing a treatment alternative. In recent years, with the publicity associated with new technology and minimally invasive treatment alternatives, the number of patients visiting their physicians to seek treatment for voiding dysfunctions has increased. As a result, we believe more patients will begin to choose treatments other than drug therapy, which may have adverse side effects, or other alternatives, which simply manage their disorder.

*Emphasis on quality of life.* Patients have placed an increased emphasis on quality of life issues and maintaining active lifestyles. Their desire to improve quality of life is usually an important factor in selecting a treatment for their disorder. We believe patients seeking treatment are increasingly considering alternatives designed to cure or treat a voiding dysfunction rather than simply manage it. As a result, we believe patients will increasingly choose minimally invasive surgical treatments or other effective treatments such as neuromodulation.

## **Uroplasty Strategy**

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

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

*Grow our United States sales and international distribution.* We believe that in addition to international market, the United States is a significant opportunity for future sales of our products. In order to grow our United States business, which represented approximately 1% of our total 2006 net sales, we recently established a sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. We anticipate further increasing our sales and marketing organization in the United States, as needed, to support our sales growth. In addition, we intend to expand our European presence by creating new distribution partnerships.

*Educate physicians and patients about the benefits of Urgent PC.* We believe education of physicians and patients regarding the benefits of Urgent PC are critical to the successful adoption of this product. To this end, we have initiated a United States multi-center randomized prospective clinical trial comparing the Urgent PC device to the most commonly prescribed pharmaceutical treatment of OAB symptoms. We believe the results of this and other studies, if successful, will allow us to expand our

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marketing and clinical sales efforts. These sales and marketing efforts may include physician training and education programs which will emphasize the clinical efficacy and ease of use of our Urgent PC product as well as patient-oriented marketing materials for physicians to use to inform patients of the availability and potential benefits of our Urgent PC product.

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

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

## **Background of Urinary Incontinence**

### ***Causes of Urinary Incontinence***

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

Male incontinence is most often associated with prostate conditions or nerve problems, such as complications arising from diabetes, stroke or Parkinson's disease. In the United States, approximately 22% of adults over age 65 with urinary incontinence are men.

### ***Types of Urinary Incontinence***

There are four types of urinary incontinence:

*Stress Urinary Incontinence* Stress urinary incontinence, or SUI, refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from ordinary physical activities, such as coughing, sneezing, laughing, straining or lifting. For the majority of women with SUI (9 million of the 11 million in the United States), incontinence is caused by urethral hypermobility. Urethral hypermobility—abnormal movement of the bladder neck and urethra—occurs when the anatomic supports for the bladder neck and urethra have weakened. This anatomical change is often the result of childbirth. Stress urinary incontinence can also be caused by intrinsic sphincter deficiency, or the inability of the sphincter valve or muscle to function properly. Intrinsic sphincter deficiency, or ISD, can be due to congenital sphincter weakness or can result from deterioration of the urethral muscular wall due to changes of aging or damage following trauma, spinal cord lesion or radiation therapy. SIU is the most common form of incontinence, accounting for almost one-half of the total worldwide prevalence of urinary incontinence.



Approximately 2 million men worldwide suffer from SUI, many of which are prostate cancer survivors who have undergone surgery for the treatment of their cancer. These reasons often restrict their activities, limit their fluid intake or change their lifestyles to deal with SUI.

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

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

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

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

### ***Management of Urinary Incontinence***

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

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

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

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

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

### ***Curative Treatment of Urinary Incontinence***

*Injectable Bulking Agents.* Urethral bulking agents are inserted with a needle into the area around the urethra, augmenting the surrounding tissue for increased capacity to control the release of urine. Hence, these materials are often called bulking agents or injectables. Urethral bulking agents may be either synthetic or biologically derived and are an attractive alternative to surgery because they are considerably less invasive and do not require use of an

operating room for placement; urethral bulking agents can be implanted in an office or out-patient facility. Active women benefit from the use of urethral bulking agents since they will often return to normal activities in a matter of days instead of weeks of recovery following invasive surgical procedures. Bulking agents also represent a desirable treatment option for the elderly or infirm who may not otherwise be able to withstand the trauma and morbidity resulting from a fully invasive surgical procedure. Additionally, the use of a urethral bulking agent does not preclude the subsequent use of more invasive treatments if required. Furthermore, for patients who have had more invasive treatments, such as slings which

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do not completely resolve their stress urinary incontinence conditions, bulking agents may be used to bring together any remaining urethral opening that may exist. This combination therapy may be particularly suitable for those patients with coexisting hypermobility issues along with intrinsic sphincter deficiency.

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

Synthetic bulking agents include solid silicone elastomers, pyrolytic carbon-coated beads, dimethyl sulfoxide (DMSO) and polyvinyl alcohol.

*Surgery.* In women, stress urinary incontinence can be corrected through surgery with a sling which provides a hammock-type support for the urethra to prevent its downward movement and the associated leakage of urine. Market adoption of sling procedures is demonstrated by over 10% annual growth during the last five years. Over 160,000 sling procedures are estimated to be performed annually in the United States, with the majority of these procedures using a tension-free sling product, usually implanted in an outpatient setting. In men, the surgical options for treating urinary incontinence are a male sling or an implanted artificial urinary sphincter. Reserved as a last resort, surgical implantation of an artificial urinary sphincter provides patient-control of a device that keeps the urethra closed until the patient is ready to urinate. Surgery to place the artificial sphincter requires general or spinal anesthesia.

## **Uroplasty Solutions for Urinary Incontinence**

We believe that we are uniquely positioned with differentiable, minimally invasive products to address urinary incontinence.

### ***Macroplastique***

Macroplastique is an injectable soft tissue-bulking agent used to treat stress urinary incontinence, the most common form of urinary incontinence in women. It is designed to restore the patient's urinary continence immediately following treatment. Additionally, men who experience incontinence as a result of prostate surgery are also candidates for Macroplastique treatment.

Macroplastique is a soft-textured, permanent implant placed endoscopically around the urethra distal to the bladder neck. It is a proprietary composition of heat vulcanized, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone) implants suspended in a biocompatible carrier gel. We believe our compound is better than other commercially available bulking agents because, with its unique composition, shape and size, it does not degrade, is not absorbed into surrounding tissues and does not migrate from the implant site. This reduces the need for follow-up treatments. Additionally, there is no need for special storage, cumbersome preparation or mixing for use, nor is there a need for patient allergy testing.

We currently market Macroplastique outside the United States on the basis that our outpatient, minimally invasive treatment can lead to lower surgical risk with shorter recovery time, and that it is less expensive when compared to invasive alternatives. Its safety and efficacy are evidenced by 14 years of successful use outside the United States with over 70,000 patients treated.

Although Macroplastique is traditionally implanted with the aid of an endoscope, we also market outside the United States a patented, non-endoscopic delivery kit called the Macroplastique Implantation System<sup>™</sup>, or MIS, for office-based treatment of female stress urinary incontinence. Our MIS enables easy and consistent product placement.

Following FDA approval of Macroplastique, we intend to seek regulatory approval for the MIS.

In December 2004, FDA accepted for filing our PMA submission with respect to Macroplastique for the treatment of female stress urinary incontinence. In September 2006, FDA advised us that our PMA application is approvable subject to FDA audit of our manufacturing facilities, methods and controls for compliance with

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applicable Quality System Requirements. FDA has completed its inspection of our manufacturing facilities in Minneapolis, Minnesota and Eindhoven, The Netherlands, with no findings noted. In October 2006, we received from FDA pre-market approval of Macroplastique. We expect to begin marketing the product in the United States in early 2007. However, we cannot ensure that we can market the product profitably.

### ***I-Stop Sling***

We believe that the I-Stop product is the only synthetic, mid-urethral sling made of monofilament knitted polypropylene with closed loop edges, making it non-damaging to surrounding tissue without the need for a delivery sheath. We also believe that the I-Stop design provides greater strength and controlled flexibility, and improved resistance to fragmentation, stretching and deformity during the outpatient implant procedure, than competitive sling devices. We believe that our tape design results in less irritation and fewer overall complications for patients. We believe our product is competitively priced and we offer components to address the retropubic and transobturator surgical approaches. The I-Stop sling has received 510(k) clearance and is CE marked for the treatment of female urinary incontinence due to urethral hypermobility.

In response to the market interest for an in-office sling, we are working in partnership with CL Medical to develop our proprietary in-office mid-urethral sling product. In addition, we are pursuing opportunities to treat male stress incontinence with our I-Stop sling. In November 2006, the I-Stop TOMS sling received 510(k) clearance for the treatment of male SUI. The I-Stop TOMS sling is also CE marked. We expect to begin marketing the I-Stop TOMS sling in early 2007.

### **Background of Overactive Bladder Symptoms**

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

### ***Treatment of Overactive Bladder Symptoms***

*Drug Therapy.* The most common treatment for OAB is drug therapy using an anticholinergic agent. However, for some individuals, the drugs are ineffective or the side effects so bothersome that the patient discontinues the medications. Common side effects include dry mouth, constipation and headaches.

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

*Neuromodulation.* Normal urinary control is dependent upon properly functioning neural pathways and coordination among the central and peripheral nervous systems, the nerve pathways, bladder and sphincter. Unwanted, uncoordinated or disrupted signals along these pathways can lead to overactive bladder symptoms. Therapy using neuromodulation incorporates electrical stimulation to target specific neural tissue and jam the pathways transmitting

unwanted signals. To alter bladder function, the stimulation must be delivered to the sacral nerve plexus, the neural tissue affecting bladder activity. Neuromodulation for OAB is presently conducted through sacral nerve stimulation or percutaneous tibial nerve stimulation.

The sacral nerve stimulator uses a small device, a neurostimulator, to send mild electrical pulses to the sacral nerve. The sacral nerve is located in the lower back, just above the tailbone. The surgically implanted neurostimulator contains a battery and electronics to create the electrical pulses and is connected to a

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neurostimulation lead (an insulated wire) containing electrodes through which stimulation is delivered to the nerve. The device is most frequently placed under the skin of the buttock, with the lead under the skin near the spine.

Alternatively, percutaneous tibial nerve stimulation (PTNS) delivers stimulation to the sacral nerve plexus by temporarily applying electrical pulses to the tibial nerve. The tibial nerve is an easily accessed nerve in the lower leg. Neuromodulation using PTNS has a similar therapeutic effect as the implantable sacral nerve stimulator, but requires no surgery. PTNS is minimally invasive, has a low risk of complication and is typically performed in a physician's office.

## **Uroplasty Solutions for Overactive Bladder Symptoms**

### ***Urgent PC Neuromodulation System***

The Urgent PC is a minimally invasive nerve stimulation device designed for office-based treatment of urge incontinence, urinary urgency and urinary frequency symptoms of an overactive bladder. Using percutaneous tibial nerve stimulation near the ankle, the product delivers an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function.

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

The Urgent PC device previously received 510(k) clearance for sale within the United States. However, following product revisions, we submitted our own 510(k) pre-market application in August 2005. We received regulatory approvals for sale of this product in the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we launched the product for sale in those markets. We developed a second generation Urgent PC product during 2006. Following CE mark approval and 510(k) clearance, we launched this product for sale in Europe in September 2006 and in the United States in October 2006.

## **Other Uroplasty Products**

We have, and are developing additional, minimally invasive products to address fecal incontinence. Our PTQ Implants offer a minimally invasive treatment for patients with fecal incontinence. They are soft-textured, permanent implants. For treatment of fecal incontinence, PTQ Implants are implanted circumferentially into the submucosa of the anal canal. Injection creates a bulking and supportive effect similar to that of Macroplastique injection for the treatment of stress urinary incontinence. The product is CE marked and currently sold outside the United States in various international markets.

In addition to urological applications, we market our proprietary tissue bulking material outside the United States for reconstructive and cosmetic plastic surgery under the trade name Bioplastique Implants and for otolaryngology vocal cord rehabilitation applications under the trade name VOX Implants.

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



## **Marketing, Distribution and Sales**

We currently sell two products in the United States – the I-Stop sling and the Urgent PC Neuromodulation system. We expect to begin marketing Macroplastique and the I-Stop TOMS sling in the United States in early 2007. We are focusing our sales and marketing efforts primarily on office-based and outpatient surgery-based urologists with significant patient volume. Our United States sales organization is made up of 5 employed Regional Sales Managers who are geographically spread around the country. Each of these Regional

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Sales Managers has been building a network of independent sales representatives in order to effectively provide sales coverage in all major markets in the United States. Currently, we have contractual relationships with 32 independent representative groups, which total 64 independent sales representatives. In addition to our field sales organization, we employ a Director of North American Sales and Marketing who has direct responsibility for our United States sales and marketing operations. We also have internal customer service and administrative support for the sales and marketing organization. We anticipate continuing to increase and refine our sales and marketing organization, as needed, to support sales growth.

Outside of the United States, in addition to the I-Stop sling and Urgent PC Neuromodulation system, we market and sell Macroplastique and related ancillary products. We sell our products primarily through a direct sales force in the United Kingdom. In all other markets we sell our products primarily through distributors. International sales managers in The Netherlands manage and train a network of distributors in approximately 40 countries, including Australia, countries within Europe and Latin America. Each of our distributors has a territory-specific distribution agreement, including requirements indicating they may not sell injectable products that compete directly with Macroplastique. Collectively, our distributors accounted for approximately 65% and 70% of total net sales for fiscal 2006 and 2005, respectively.

We use clinical studies and scientific community awareness programs to demonstrate the safety and efficacy of our products. This data is important to obtain regulatory approval and to support our sales staff and distributors in securing product reimbursement in their territories. Publications of clinical data in peer-reviewed journals add to the scientific community awareness of our products, including patient indications, treatment technique and expected outcomes. Our clinical research department provides a range of activities designed to support surgeons in their clinical evaluation study design, abstract preparation, manuscript creation and review and submission. This team works closely with our sales and marketing and regulatory departments in the area of technical support, submissions, literature review, and analysis and synopsis of technical presentations and publications.

Researchers have designed clinical trials to provide outcome evidence on new products recently developed by us. These include randomized controlled clinical trials on our PTQ Implants, Macroplastique Sling Support Kit (MIS-SK) and a United States multi-center randomized prospective study comparing the Urgent PC device to the most commonly prescribed pharmaceutical treatment of OAB symptoms. Evidence-based clinical research broadens the surgeons acceptance by providing detailed information related to product safety and efficacy when applied to patient selection and comparative surgical and non-surgical treatment regimens, and publication of the clinical outcome will provide physicians, patients and reimbursement systems with the evidence they require to make informed decisions.

## **Distribution Agreements**

### ***CL Medical***

We are the exclusive distributor in the United Kingdom of the I-Stop, a biocompatible, tension-free, mid-urethral sling manufactured by CL Medical SAS of Lyon, France. In February 2006, we entered into a new distribution agreement with CL Medical which replaces and supersedes the manufacturing and distribution agreement dated September 2, 2004. The new distribution agreement appoints us as the exclusive distributor of the I-Stop sling in the United States, and obligates CL Medical to supply us with the product's entire requirements, sterilized, packaged, labeled and ready for sale, all manufactured in accordance with FDA laws and regulations. The new distribution agreement is for six years, with our right to renew it for successive five-year terms. If we fail to reach our minimum purchase requirement in any 12-month period, CL Medical has the right to terminate our exclusive distribution rights in the United States.

Under the new distribution agreement, CL Medical has agreed to provide us with any improvements or modifications it makes to the I-Stop sling during the term of the agreement without additional charge. In addition, CL Medical has

granted us a right of first refusal for exclusive distribution rights in the United States to any new medical devices or procedures it develops during the term of the agreement. We have agreed that during, and for one year after, the term of our agreement, we will not manufacture our own, or market any other party's tension-free vaginal tape product for the treatment of female stress urinary incontinence. If for

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some reason CL Medical is prohibited from exporting the I-Stop sling into the United States, CL Medical is required to supply us with the components necessary to manufacture, package and label the I-Stop sling for the United States market.

In May 2005, we entered into a one-year exclusive distribution agreement with CL Medical for the United Kingdom. The agreement is renewable for up to 2 years, subject to certain performance requirements of us to distribute the I-Stop sling in Great Britain.

Under the agreements with CL Medical, one of which was modified in October 2006, we are required to purchase a minimum of \$527,000 of units in the first 12-month period following January 1, 2006, increasing to \$2.7 million of units in the fifth year of the agreement, for an aggregate commitment of approximately \$6.9 million of units over the five-year period, subject to periodic adjustment based on the value of the euro. The purchase price is payable in euros.

### ***CystoMedix***

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix, Inc., an Andover, Minnesota medical device company, to license the exclusive rights to manufacture and market the Urgent PC device for the United States, Canada and all countries recognizing the CE mark. Under our agreement with CystoMedix, we are responsible for regulatory applications and compliance within all markets outlined in the agreement. Although the Urgent PC as marketed by CystoMedix was CE marked and 510(k) cleared, following minor revisions to the product, we secured 510(k) clearance for our device in October 2005 and CE mark approval in November 2005. In 2006, we developed a second generation Urgent PC and received 510(k) clearance, CE mark approval and Canadian regulatory approval to sell our second generation Urgent PC system. We launched this product for sale in Europe in September 2006 and in the United States in October 2006 and initiated trade-out programs to exchange the old device with the new device. Our new device provides an enhanced user interface, programmed treatment settings, visual and auditory feedback during device operation.

Our agreement with CystoMedix is for five years, with no right to renew it. In connection with the agreement, we purchased 75% of CystoMedix's inventory of component parts and subassemblies for \$25,000. We paid an initial royalty payment of \$225,000 in May 2005 and paid an additional aggregate of \$250,000 in royalties in monthly installments through May 2006. During the agreement's term, we also will pay CystoMedix further royalties of 7% of our net product revenues from the sale of licensed products, offset by payments made against the above \$250,000 amount. We have agreed to sell licensed products we manufacture back to CystoMedix, on a non-exclusive basis, on terms and for such price as we may mutually negotiate for CystoMedix's own sales outside of the territories exclusively licensed to us.

Between January 2006 and June 2008, we may elect to purchase all of CystoMedix's assets. The option price is \$3,485,000, reduced by up to \$50,000 of liabilities assumed by us. However, the \$3,485,000 amount used to compute the option price will increase at a rate of 10% per year after April 2007. The option price is payable in shares of our common stock valued at the average of the closing bid price of our shares for the 20 trading days prior to our exercise of the option. If we exercise our option, we will also assume up to \$1.4 million of bridge loan advances made to CystoMedix by its Chairman. We would repay up to \$1.1 million of the bridge loan advances at closing and would issue our common stock for the balance of the bridge loan based on the above option price. We also have certain rights of first refusal to acquire CystoMedix's assets in the event CystoMedix receives a third party offer in advance of any exercise of our option.

### **Manufacturing and Suppliers**

We manufacture our tissue bulking products at our own facilities. Components are manufactured in the United States, and finished products are manufactured in The Netherlands. Our facilities utilize dedicated heating, ventilation and high efficiency particulate air (HEPA) filtration systems to provide a controlled working environment. Trained production technicians perform all critical manufacturing processes in a cleanroom environment according to established written procedures. An outside vendor sterilizes our products using validated methods and returns the products to us for final inspection and testing.

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Our manufacturing facilities and systems are periodically audited to ensure compliance with ISO 13485 (medical device quality management systems), and applicable European and Canadian medical device requirements. Our European facilities and systems were last audited by AMTAC Certification Services in October 2006. No major deficiencies were noted, and we were found to be in compliance with all standards and requirements audited. Prior to marketing our products in the United States, our facilities need to be compliant with FDA's Quality System Regulations and will be subject to additional state, local, and federal government regulations applicable to the manufacture of our products. In connection with its review of our pre-market approval application for Macroplastique, FDA recently completed its inspection of our manufacturing facilities in Minneapolis, Minnesota and Eindhoven, The Netherlands, with no findings noted.

CL Medical in Lyon, France manufactures the I-Stop sling. Pursuant to our distribution agreement with CL Medical, we are the exclusive distributor of the I-Stop sling in the United States and the United Kingdom. Among other things, we are required to purchase a minimum number of I-Stop product sets from CL Medical. We have minimum purchase requirements of \$527,000 of units in the first 12-month period following January 1, 2006, increasing to approximately \$2.7 million of units over a five-year period, subject to periodic adjustment based on the value of the euro. CL Medical has agreed to supply us the I-Stop sling with the product's entire requirements, sterilized, packaged, labeled and ready for sale, all manufactured in accordance with FDA laws and regulations. The agreement has an initial term of six years, with successive five-year renewal terms at our option.

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

We purchase medical grade materials for use in our finished products from single source suppliers. Our quality department has qualified these suppliers. Although we believe our sources of supply could be replaced if necessary without due disruption, it is possible that the process of qualifying suppliers for certain raw materials could cause an interruption in our ability to manufacture our products, which could have a negative impact on sales. In fact, one of the suppliers of a component material of our Macroplastique product recently ceased production of this material. We have located an alternative supplier.

## **Competition**

The market for voiding dysfunction products is intensely competitive. We face competition from existing manufacturers of management and curative treatments, competing manufacturers of commercially available bulking agents, sling products and neurostimulation devices, drug companies and firms developing new or improved treatment methods. We believe the principal decision factors among treatment methods include physician and patient acceptance of the method, with increasing preferences for minimally invasive and office-based therapies, therapeutic cost, availability of third party reimbursement, marketing and sales capability and the existence of meaningful patent protection. Our ability to compete in this market will also depend on the consistency of our product quality as well as delivery and product pricing. Other factors within and outside our control include our product development and innovation capabilities, clinical study results, ability to obtain required regulatory approvals, ability to protect our proprietary technology, manufacturing and marketing capabilities and ability to attract and retain skilled employees.

Soft-tissue injectable bulking agents competing directly with Macroplastique both outside and in the United States include Contigen® and Tegress®, both FDA-approved bulking agents manufactured by C.R. Bard, Inc.; Zuidex® and Deflux® (Deflex FDA approved for VUR use only) manufactured by Q-Med AB; Durasphere® (FDA-approved for female SUI) manufactured by Carbon Medical Technologies; and Coaptite® manufactured by BioForm, Inc. In contrast to the products currently approved for sale both inside and outside this country, Macroplastique, marketed outside the United States since 1991, is a synthetic material that will not degrade, become resorbed or migrate, and

does not require the patient to have a skin test prior to the procedure. The silicone-elastomer material has been studied for over 50 years in medical use for such urological applications as penile implants, stents and catheters. Our patented Macroplastique Implantation

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System offers a unique, non-endoscopic, minimally invasive outpatient procedure that can be performed in the physician's office.

Sling procedures have become the preferred method for treating urethral hypermobility. The tension-free sling market is dominated by Gynecare's TVT Tension-free Support device. Other companies competing in this market include American Medical Systems, C.R. Bard, Boston Scientific and Coloplast A/S. We believe our current I-Stop sling offers benefits of multiple surgical approaches for the physician and a tape design to resist stretching, deformity (i.e., preventing the cord effect) and fragmentation. In partnership with CL Medical, we are developing an in-office sling product to meet changing market requirements.

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

Many medications treat urge incontinence, some by preventing unwanted bladder contractions, others by tightening the bladder or urethra muscles and some by relaxing bladder muscles. Sometimes, these drugs have unwanted side effects such as dry mouth, vision problems or urine buildup. Among these medications are Detrol® (Pfizer Inc.), Ditropan® (Alza Corporation) and Flomax® (Abbott Laboratories).

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

## **Government Regulation**

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

### ***United States***

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

    fines, injunctions, and civil penalties;

    recall or seizure of products;

    operating restrictions, or total or partial suspension of production;



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

withdrawal of existing approvals; and

criminal prosecution.

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

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clearance. Devices deemed by FDA to pose the greatest risk (Class III devices), such as life-sustaining, life-supporting or implantable devices, or a device deemed not to be substantially equivalent to a previously cleared 510(k) device, require the submission of a pre-market approval application. FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

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

After a device receives 510(k) clearance for a specific intended use, modifications or enhancements that could significantly affect the safety or effectiveness of the device or that would constitute a major change to the intended use of the device will require a new 510(k) pre-market notification submission or could require pre-market approval. FDA requires each manufacturer to make this determination initially, but FDA can review any such decision. If FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, FDA can require the manufacturer to cease marketing or recall the modified device until 510(k) clearance or pre-market approval is obtained. Also, in these circumstances, a company may be subject to significant regulatory fines or penalties.

*Pre-market Approval.* A pre-market approval, or PMA, application must be submitted if the device cannot be cleared through the 510(k) process. The PMA process is much more demanding than the 510(k) notification process. A PMA applicant must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. As part of the PMA process, applicants must file an Investigational Device Exemption, or IDE, application prior to commencing human clinical trials. If the IDE application is approved by FDA, human clinical trials may begin at a specific number of investigational sites with a maximum number of patients. The results of clinical testing may not be sufficient to obtain approval of the product.

After FDA determines that a PMA submission is complete, FDA accepts the submission and begins an in-depth review of the submitted information. FDA, by statute and regulation, has 180 days to review an accepted PMA submission, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, FDA may request additional information, testing or clarification of information already provided. Also during this review period, an advisory panel of experts from outside FDA may be convened to review and evaluate the application and provide recommendations to FDA as to the approvability of the device. In addition, FDA will conduct clinical inspections at investigational sites and a pre-approval inspection of the manufacturing facility to ensure compliance with FDA's Quality System Regulations. New PMA submissions or supplemental PMA submissions are required for significant modifications to the manufacturing process, labeling, use and design of a device that is approved through the PMA process. Pre-market approval supplements often require submission of the same type of information as a PMA submission, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA submission, and may not require as extensive clinical data or the convening of an advisory panel.

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

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

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

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medical device reporting regulations, which require that manufacturers report to FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and

notices of correction or removal, and recall regulations.

*FDA Approval Status of Our Products.* FDA has determined that urethral bulking agents, such as Macroplastique, are Class III devices and require FDA clearance of a pre-market approval submission. In 1999, FDA approved our IDE application with respect to Macroplastique for the treatment of female stress urinary incontinence. In 2000, we commenced a multi-center human clinical trial using Macroplastique in a minimally invasive, office-based procedure for treating female stress urinary incontinence resulting from internal sphincter deficiency, or a weakening of the muscles that seal off the flow of urine. In December 2004, FDA accepted for filing our pre-market approval submission with respect to Macroplastique for the treatment of female stress urinary incontinence. In September 2006, we received an approvable letter from FDA relating to our pre-market approval application for Macroplastique Implants. The receipt of the approvable letter follows FDA's completion of the scientific review of the safety and efficacy of Macroplastique. FDA determined that our pre-market approval application is approvable subject to FDA audit of our manufacturing facilities, methods and controls for compliance with applicable Quality System Requirements. FDA completed its inspection of our manufacturing facilities in Minneapolis, Minnesota and Eindhoven, The Netherlands, with no findings noted. In October 2006, we received pre-market approval of Macroplastique. We expect to begin marketing the product in the United States in early 2007. Following market introduction, we will conduct customary, FDA-required post-approval studies to obtain market feedback on safety and effectiveness of the product.

In August 2005, the I-Stop sling for the treatment of female SUI received 510(k) clearance for sale within the United States. In November 2006, the I-Stop sling for the treatment of male SUI received 510(k) clearance for sale within the United States.

The Urgent PC device previously received 510(k) clearance for sale within the United States. However, following product revisions, we submitted our own 510(k) pre-market application in August 2005. In October 2005, our initial version of the Urgent PC device received 510(k) clearance for sale within the United States. In July 2006, our second generation Urgent PC device received 510(k) clearance for sale within the United States.

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

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

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

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

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

Our manufacturing facilities and processes have been inspected and certified in compliance with ISO 13485, applicable European medical device directives and Canadian Medical Device Requirements. FDA is currently auditing our manufacturing facilities for compliance with Quality System Regulations. We cannot ensure you that our facilities and processes will be found to comply with Quality System Regulations and there is a risk that approval will,

therefore, be delayed by FDA until such compliance is achieved.

***European Union and Other Regions***

The European Union has adopted rules that require that medical products receive the right to affix the CE mark, which stands for Conformité Européenne. The CE mark demonstrates adherence to quality assurance

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standards and compliance with relevant European medical device directives. Products that bear the CE mark can be imported to, sold or distributed within, the European Union.

We received CE marking approval for Macroplastique in 1996 for the treatment of male and female stress urinary incontinence and vesicoureteral reflux; for VOX in 2000 for vocal cord rehabilitation applications; for PTQ in 2002 for the treatment of fecal incontinence; and for Bioplastique in 1996 for dermal augmentation applications. Our manufacturing facilities and processes have been inspected and certified by AMTAC Certification Services, a recognized Notified Body, testing and certification firm based in the United Kingdom. The I-Stop sling for the treatment of female SUI received CE marking approval in July 2002. CystoMedix, the company that granted us rights to manufacture and distribute the Urgent PC nerve stimulation device, obtained its own CE mark. Our initial version of the Urgent PC device received CE marking approval in November 2005. Our second generation Urgent PC device received CE marking approval and approval from the Canadian Therapeutic Products Directorate of Health in June 2006.

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

## **Third-Party Reimbursement**

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

In the United States, third-party payors consist of government programs, such as Medicare, private health insurance plans, managed care organizations and other similar programs. For any product, three factors are critical to reimbursement:

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

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

payment amount.

Reimbursement for tension-free sling products has been addressed by numerous competitors. As a result, coding, coverage and payment for the I-Stop is already well established.

As a relatively new therapy, nerve stimulation using the Urgent PC has not been assigned a reimbursement code unique to the technology. However, a number of practitioners are using an existing reimbursement code that closely describes the procedure. In addition, Aetna and Blue Cross Blue Shield of Minnesota and Maryland have published policies providing coverage for PTNS under an existing reimbursement code. We will need to continue to work with

third-party payers for coverage policies and the American Medical Association to develop definitive and uniform reimbursement for the therapy. In addition, we will need to provide customer reimbursement as we market the product and secure medical community acceptance.

We believe there are appropriate codes available to describe endoscopic use of Macroplastique to treat female SUI. We expect we will need to foster coverage policies and payer acceptance to support the United

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States launch of Macroplastique. There is no guarantee that Macroplastique will be reimbursed at the levels expected by us, if at all.

## **Patents, Trademarks and Licenses**

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

We hold multiple patents covering our Macroplastique materials, processes and applications. As of the date of this prospectus, we have four issued patents in the United States and 19 granted patents in the United Kingdom, Japan, Germany, France, Spain, Italy, Portugal, The Netherlands and Canada. Our patents will expire in the United States at various times between 2011 and 2016 and in other countries between 2009 and 2017. There can be no assurance any of our issued patents are of sufficient scope or strength to provide meaningful protection of our products. In addition, there can be no assurance any current or future United States and foreign patents of ours will not be challenged, narrowed, invalidated or circumvented by competitors or others, or that our patents will provide us with any competitive advantage. Any legal proceedings to maintain, defend or enforce our patent rights could be lengthy and costly, with no guarantee of success. CystoMedix and CL Medical also have certain patent rights which they licensed to us as part of their respective manufacturing and distribution agreements. We also have pending United States patent applications with respect to our second generation Urgent PC.

In 1992, we agreed to settle alleged patent infringement claims by Collagen Corporation (now Inamed Corporation). Under the settlement agreement, we paid Collagen a royalty of 5% of net sales in the United States of Macroplastique products with a minimum of \$50,000 per year. The agreement terminated on May 1, 2006.

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

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

We have registered Macroplastique and Bioplastique as trademarks with the U.S. Patent and Trademark Office. Our non-registered trademarks include VOX and PTQ, for which trademark registration applications are pending in the U.S. Patent and Trademark Office. CystoMedix has U.S. registration of the Urgent PC trademark and has licensed the mark to us as part of our exclusive manufacturing and distribution agreement. In addition, CL Medical has licensed its non-registered trademark for the I-Stop sling to us as part of our agreement with it.

We have a royalty agreement with three individuals, two of whom are former officers and directors. Under this royalty agreement, we pay aggregate royalties of 3 to 5% of net sales of Macroplastique and Bioplastique, subject to a monthly minimum of \$4,500. The royalties payable under this agreement will continue until the patent referenced in the agreement expires in 2010.

In October 1998, we received an absolute assignment from a British surgeon of a worldwide patent relating to the Macroplastique Implantation System in return for a royalty of £10 for each unit sold during the life of the patent. We



began commercialization of the product outside the United States in March 2000.

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### **Research and Development**

We have a research and development program to develop new incontinence products. We are also continually evaluating potential improvements to our products as well as new methods and devices. Research and development expenses also include the costs of clinical studies and regulatory compliance. Our expenditures for research and development totaled approximately \$3.3 million for fiscal 2006 and approximately \$2.3 million for fiscal 2005. None of these costs were borne directly by our customers.

### **Product Liability**

The medical device industry is subject to substantial litigation. As a manufacturer of a long-term implantable device, we face an inherent risk of liability for claims alleging adverse effects to the patient. We currently carry \$2 million of worldwide product liability insurance, plus another policy specific to the United Kingdom only. There can be no assurance, however, our existing insurance coverage limits are adequate to protect us from any liabilities we might incur. There can be no assurance that liability claims will not exceed coverage limits. Product liability insurance is expensive and in the future may not be available to us on acceptable terms, if at all. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any product recall. A successful claim in excess of our insurance coverage could materially deplete our assets. Moreover, any claim against us could generate negative publicity, which could decrease the demand for our products and our ability to generate revenues.

### **Compliance with Environmental Laws**

Compliance by us with applicable environmental requirements during fiscal years 2006 and 2005 has not had a material effect upon our capital expenditures, earnings or competitive position.

### **Dependence on Major Customers**

During fiscal 2006, two customers individually accounted for approximately 14% and 11% of our net sales. During fiscal 2005, the same two customers individually accounted for approximately 15% and 11% of our net sales.

### **Employees**

As of October 9, 2006, we had 51 employees, of which 49 were full-time and 2 were part-time. No employee has a collective bargaining agreement with us. We believe we maintain good relations with our employees.

### **Properties**

Effective May 1, 2006, we moved our corporate headquarters to a 18,258 square foot facility located in Minnetonka, Minnesota. The Minnetonka property is subject to a lease that extends for a term of 96 months. We own 9,774 square feet of office and warehouse space in Geleen, The Netherlands. We will vacate our 6,205 square foot facility in Minneapolis, Minnesota, by the end of October 2006. We also lease 5,800 square feet of office, warehouse, laboratory and manufacturing space through June 2012 in Eindhoven, The Netherlands.

### **Legal Proceedings**

We are not currently a party to any pending legal proceeding.

**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table sets forth the name, age and position of each of our executive officers and directors:

<b>Name</b>	<b>Age</b>	<b>Position</b>
R. Patrick Maxwell	62	Chairman
David B. Kaysen	57	President, Chief Executive Officer and Director
Thomas E. Jamison	46	Director
Lee A. Jones	49	Director
James P. Stauner	52	Director
Sven A. Wehrwein	55	Director
Mahedi A. Jiwani	58	Vice President, Chief Financial Officer and Treasurer
Susan Hartjes Holman	52	Chief Operating Officer and Secretary
Larry Heinemann	54	Vice President Sales & Marketing
Arie J. Koole	42	Controller and Managing Director Dutch subsidiaries
Marc M. Herregraven	41	Vice President of Manufacturing

*R. Patrick Maxwell* has served as Chairman of our Board since June 2006 and has served as a director of our company since April 1994. Mr. Maxwell has over 30 years of experience as a turn around management specialist, an entrepreneur and executive in both the business and non-profit sectors. Mr. Maxwell has been CEO of Entronix Inc. since November 2005. Mr. Maxwell is cofounder and a director of Telnet Services Limited of Auckland, New Zealand since September 1995, cofounder and Chief Financial Officer of Tele Resources, Inc. since October 1996 and Chief Financial Officer of Magnum Tire Corporation since March 2003. Mr. Maxwell has served on numerous boards of directors of both business and charitable organizations. He has a B.A. in philosophy from St. John's University and a J.D. from Northwestern University School of Law.

*David B. Kaysen* has served as our President and Chief Executive Officer and as a director since May 2006. From July 2005 to May 2006, Mr. Kaysen served as President, Chief Executive Officer and a director of Advanced Duplications Services, LLC, a privately-held replicator and duplicator of optical media, such as CDs and DVDs. Between December 2002 and June 2005, he served as President, Chief Executive Officer and a director of Diametrics Medical, Inc., then a publicly-traded manufacturer and marketer of critical care blood analysis systems that provide continuous diagnostic results at point of care. From 1992 to 2002, Mr. Kaysen served as Chief Executive Officer, President and a director of Rehabiliticare Inc., since renamed Compex Technologies, Inc., a publicly-traded manufacturer and marketer of electromedical rehabilitation and pain management products for clinician, home and industrial use. Mr. Kaysen currently serves on the board of directors of MedicalCV, Inc. and Zevex International. Mr. Kaysen holds a B.S. in Business Administration from the University of Minnesota.

*Thomas E. Jamison* became a director of our company in August 2000. Mr. Jamison is a shareholder of Fruth, Jamison & Elsass, P.A., a business litigation firm in Minneapolis, Minnesota. From 1996 to 1999, Mr. Jamison served as an investment banker in the Corporate Finance Department of R.J. Steichen & Company. From 1991 to 1996, Mr. Jamison practiced law at Fruth & Anthony, P.A. in Minneapolis. Mr. Jamison graduated magna cum laude from William Mitchell College of Law in 1991.

*Lee A. Jones* has been a director of our company since August 2006. She has more than 20 years of healthcare and medical device industry experience. Since 1997, she has served as President and Chief Executive Officer of Inlet Medical, Inc. (a Cooper Surgical company since November 2005), specializing in minimally interventional laparoscopic products. Prior to joining Inlet, she had a 14-year career at Medtronic, Inc., where she held various technical and operating positions, most recently serving as Director, General

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Manager of Medtronic Urology/Interstim division. Ms. Jones currently serves as a member of the Board of Directors of Impress Medical, Inc. She holds a B.S. in Chemical Engineering from the University of Minnesota.

*James P. Stauner* has been a director of our company since August 2006. Mr. Stauner has over 27 years of experience in the healthcare industry. Since July 2005, he has been the Operating Principal with Roundtable Healthcare Partners, a private equity firm focused on the healthcare industry. Prior to joining Roundtable Healthcare Partners, Mr. Stauner held various positions between 1999 and 2005 at Cardinal Health, Inc., most recently as President of the Manufacturing Business Groups and a member of the Senior Management Operating Committee. He holds a B.S. in Business Administration from the University of Illinois.

*Sven A. Wehrwein* has been a director of our company since August 2006. He has over 25 years of experience in corporate finance and investment banking, including serving as Chief Financial Officer of InStent Inc. and Digi International. Since 1999, he has provided financial-consulting services to emerging growth companies. Mr. Wehrwein also serves on the Board of Directors of Vital Images, Inc., Synovis Life Technologies, Inc., Image Sensing Systems, Inc. and Van Wagoner Funds, Inc. He holds a Masters of Management degree in Finance from the Sloan School at the Massachusetts Institute of Technology and is a Certified Public Accountant

*Mahedi A. Jiwani* has served as our Vice President, Chief Financial Officer and Treasurer since November 2005. From 2003 to 2005, Mr. Jiwani served as Chief Financial Officer of M.A. Gedney Company, a Minnesota-based food products distributor. Between 1997 and 2003, he was employed by Telex Communications, Inc., most recently as Vice President of Finance. Mr. Jiwani holds an M.B.A. and a Master of Engineering from the University of Minnesota.

*Susan Hartjes Holman* has served as our Chief Operating Officer since November 2002 and as Secretary since September 1996. She served as our Vice President of Operations and Regulatory Affairs from November 1994 to October 2002. She joined Bioplasty, Inc. in September 1991 as Director of Operations and served as Vice President of Operations and Regulatory Affairs from April 1993 until May 1996. Ms. Holman was Director of Operations at Bio-Vascular, Inc. in St. Paul, Minnesota from November 1989 to September 1991. Prior to that time, she served at various other pharmaceutical and medical device companies in management positions in manufacturing, quality assurance, and research. Ms. Holman has B.A. degrees in Biology-Microbiology and Biomedical Science from St. Cloud State University, and has done graduate work in the biological sciences. Ms. Holman is a Senior Member and a Certified Quality Auditor of the American Society for Quality, has served several years on its Executive Committee and subcommittees, and is a member of the Regulatory Affairs Professionals Society and its Ethics Task Force, and the Henrici Society for Microbiologists. She has served on several national and international scientific and regulatory committees, and is a cofounder for the Biomedical Focus Conference and the Biomedical Consortium, Minneapolis, Minnesota.

*Larry Heinemann* joined us in September 1998 as Director of Sales for North and South America. In July 1999, Mr. Heinemann was promoted to Vice President of Sales and Marketing and in August 2001, he was appointed as Vice President of Marketing & Corporate Development. In August 2003, he was again appointed to his current position as our Vice President of Sales and Marketing. Mr. Heinemann holds a B.S. in marketing and personnel management from the School of Business of Eastern Illinois University.

*Arie J. Koole* joined Bioplasty B.V. in May 1993 as Financial Manager in The Netherlands. Since January 2000, he has been the Managing Director of our subsidiaries in The Netherlands. In June 1996, Mr. Koole was appointed as Director of Finance and in January 2000, Mr. Koole was appointed as our Controller. From 1987 to 1993, Mr. Koole was a financial auditor with the international accounting firm Deloitte & Touche in The Netherlands. Mr. Koole has a bachelors degree in Business Economics.

*Marc M. Herregraven* has served as our Vice President of Manufacturing since November 2002. He joined Bioplasty, Inc. in April 1992 as Plant Manager, and became Director of Manufacturing in 1994 and Director of Operations in 1999. Previously, he served with Advanced Bio-Surfaces, Inc., a Minnesota-based medical device developer, as Director of Manufacturing, and with Bio-Vascular, Inc., a Minnesota-based

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medical device manufacturer, in an engineering function. Mr. Herregraven has a B.S. in Mechanical Engineering and has been a member of the American Society for Quality since 1996.

## **Board Composition**

Our board of directors currently consists of five directors and is divided into three classes. The members of each class serve for a three-year term. At each annual meeting of shareholders, a class of directors will be elected for a three-year term.

## **Corporate Governance**

### ***Compensation Committee***

The members of our Compensation Committee are Messrs. Jamison (Chair) and Stauner and Ms. Lee. The function of the Compensation Committee is to set the compensation for officers, to set the terms of and grants of awards under our stock option plans and to act on other matters relating to compensation as the committee deems appropriate.

### ***Audit Committee***

The members of our Audit Committee are Messrs. Wehrwein (Chair), Maxwell and Jamison. The Audit Committee assists the board by reviewing the integrity of our financial reporting processes and systems of internal controls, the qualifications, independence and performance of our independent registered public accounting firm and our compliance with certain legal and regulatory requirements. Our Audit Committee has the sole authority to retain, compensate, oversee and terminate our independent registered public accounting firm. The Audit Committee reviews our annual audited consolidated financial statements, quarterly consolidated financial statements and filings with the SEC. The Audit Committee reviews reports on various matters, including our critical accounting policies, significant changes in our selection or application of accounting principles and our internal control processes. The Audit Committee also pre-approves all audit and non-audit services performed by our independent registered public accounting firm.

Our board of directors has determined that all members of the Audit Committee are independent directors under SEC rules and has determined that Mr. Wehrwein qualifies as an audit committee financial expert under the rules of the SEC.

### ***Nominating Committee***

Our board of directors created a Nominating Committee effective October 1, 2005. The members of our Nominating Committee are Messrs. Maxwell (Chair) and Stauner and Ms. Jones. The purpose of the Nominating Committee is to identify qualified individuals for membership on the board and recommend to the board the nominees for election at our annual meetings of shareholders.

Our board of directors and the Nominating Committee believe the committee's current member composition satisfies the American Stock Exchange's ( AMEX ) rule governing committee composition, including the requirement that committee members all be independent directors as that term is defined by AMEX rules.

### ***Code of Ethics***

We have adopted a Code of Ethics that applies to all of our directors, officers and employees, including our Chief Executive Officer, Chief Financial Officer, Controller and other finance organization employees. The Code of Ethics

is publicly available as an exhibit to our Annual Report on Form 10-KSB for the year ended March 31, 2004.



**Table of Contents****Director Compensation**

During fiscal 2006, we paid non-employee independent board members \$500 per board meeting and \$500 per Audit Committee meeting attended. In addition, directors participated in our stock option plan.

On August 16, 2006, the Board adopted a new compensation plan for non-employee directors. All non-employee directors receive an annual fee of \$10,000 payable in cash in four equal quarterly installments of \$2,500, and attendance fees of \$1,000 per in-person board meeting, \$500 per telephonic board meeting, and \$500 per committee meeting. In addition, the Chairs of the Board, Audit Committee and Compensation Committee are paid an additional annual fee of \$1,500, \$750 and \$500 per year, respectively, payable in the quarter of appointment.

All non-employee directors also receive an automatic grant of stock options upon such director's initial appointment or election to the Board for 45,000 shares of common stock, one-third of which vests on the date of grant and the first and second anniversaries thereafter. Each non-employee director will be granted an annual stock option for 15,000 shares of common stock all of which are vested on the date of grant, except that such annual grant does not commence for newly appointed or elected directors until one year following full vesting of the initial grant.

On August 28, 2006, in connection with their initial appointment to our board, we granted to each of Ms. Jones, Mr. Stauner and Mr. Wehrwein an option to purchase 45,000 shares of our common stock at an exercise price of \$1.82 per share.

We pay no additional remuneration to Mr. Kaysen for serving as director.

Mr. Pitlor, a former director, received \$2,000 per month as consulting fees from us under an annually renewable consulting agreement dated January 2, 2002. This contract terminated effective June 30, 2005.

**Executive Compensation**

The following table sets forth, in summary form, the compensation earned in fiscal years 2006, 2005 and 2004 by our Chief Executive Officers and each of the other four most highly compensated executive officers (whom we refer to collectively as the "named executive officers"). Mr. Kaysen joined us as our President and Chief Executive Officer in May 2006.

**Summary Compensation Table**

Name and Principal Position	Fiscal Year	Annual Compensation		Long Term Compensation Awards Securities Underlying
		Salary (\$)	Bonus (\$)	Options (#)
Sam B. Humphries(1) <i>Former President and CEO</i>	2006	241,961	88,880	
	2005	50,558	29,875	400,000
Daniel G. Holman(2) <i>Former Chairman, CEO and CFO</i>	2006	251,364		
	2005	224,019		100,000
	2004	212,192		

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Mahedi A. Jiwani(3) <i>Vice President, CFO and Treasurer</i>	2006	60,577	15,050	100,000
Susan Hartjes Holman <i>COO</i>	2006	164,231		
	2005	153,692		75,000
	2004	145,754		
Arie J. Koole <i>Controller</i>	2006	139,428		
	2005	137,219		50,000
<i>Managing Director Dutch subsidiaries</i>	2004	120,546		
Larry Heinemann <i>VP Sales &amp; Marketing</i>	2006	142,691	26,782	
	2005	106,346	17,960	75,000
	2004	91,692	15,500	

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- (1) Mr. Humphries served as our President and Chief Executive Officer from January 1, 2005 to April 26, 2006.
- (2) Mr. Holman resigned as our President and Chief Executive Officer effective January 1, 2005 and as our Chief Financial Officer effective November 2005. Mr. Holman continued to serve as a director until he passed away on June 1, 2006.
- (3) Mr. Jiwani joined us as our Vice President, Chief Financial Officer and Treasurer in November 2005.

**Option Grants in Fiscal 2006**

The following table sets forth information concerning options granted to each of the named executive officers during fiscal year 2006. The outstanding options listed below may be exercised only upon the vesting of the options. Mr. Jiwani's options are 100% vested.

**Option Grants in Fiscal 2006**

Name	Number of Securities Underlying Options Granted	Individual Grants		Exercise Price (\$/Unit)	Expiration Date
		Percentage of Total Options Granted to Employees in Fiscal 2006			
Sam B. Humphries					
Daniel G. Holman					
Mahedi A. Jiwani	100,000	30%		3.00	11/14/2015
Susan Hartjes Holman					
Arie J. Koole					
Larry Heinemann					

**Option Exercises in Fiscal 2006 and Fiscal Year-End Option Values**

None of our named executive officers exercised stock options during fiscal 2006. The following table sets forth the number of shares of common stock subject to options and the value of those options held by each of the named executive officers as of March 31, 2006. The table assumes a per share price of \$2.34, which was the closing bid price on March 31, 2006.

Name	Shares Acquired on Exercise	Value Realized (\$)	Number of Securities Underlying Unexercised Options at Fiscal Year End		Value of Unexercised In-the-Money Options at Fiscal Year End (\$)	
			Exercisable	Unexercisable	Exercisable	Unexercisable

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Sam B. Humphries	468,000	12,000	1,620	1,080
Daniel G. Holman	180,000		62,000	
Mahedi A Jiwani	100,000			
Susan Hartjes Holman	117,000	8,000		