UROPLASTY INC
Form SB-2
September 14, 2005

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As filed with the Securities and Exchange Commission on September 14, 2005
Registration No. 333-

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

FORM SB-2
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

UROPLASTY, INC.
(Exact Name of Registrant as specified in its charter)

Minnesota	**3841**	**41-1719250**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

2718 Summer Street N.E.
Minneapolis, Minnesota 55413-2820
Telephone: (612) 378-1180
(Address, including zip code and telephone number, including area code, of Registrant s principal executive offices)

Sam B. Humphries
President and Chief Executive Officer
2718 Summer Street N.E.
Minneapolis, Minnesota 55413-2820
Telephone: (612) 378-1180
Facsimile: (612) 378-2027
(Name, address, including zip code and telephone number, including area code, of agent for service)

Copies to:
Jeffrey C. Robbins, Esq.
Messerli & Kramer P.A.
150 South Fifth Street, Suite 1800
Minneapolis, Minnesota 55402
Telephone: (612) 672-3600
Facsimile: (612) 672-3777

Approximate date of commencement of proposed sale to the public:
As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, par value $0.01 per share, issuable upon exercise of warrants	706,218	$2.00	$1,412,436	$166.00
Common Stock, par value $0.01 per share, issuable upon exercise of warrants	50,000	$3.00	$150,000	$18.00
Common Stock, par value $0.01 per share, issuable upon exercise of warrants	50,000	$5.00	$250,000	$29.00

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where an offer or sale is not permitted.

Subject to Completion Dated September 14, 2005.

PROSPECTUS

UROPLASTY, INC.
806,218 Shares of Common Stock
Issuable Upon Exercise of Warrants

We are offering up to 706,218 shares of our common stock issuable upon the exercise of warrants that were previously issued at no charge to existing shareholders. Holders of warrants are entitled to purchase one share of common stock for every warrant held at an exercise price of $2.00 per share The warrants are exercisable beginning on the date of this prospectus and will expire at 5:00 p.m., Minneapolis time, on ___, 2005. If all of the warrants are exercised in this offering, the total purchase price for all of the common stock sold will be $1,412,436.

This Prospectus also relates to 100,000 shares of common stock that may be sold at various times by a certain selling shareholder. We will not receive any proceeds from the sale of those shares by the selling shareholder.

Our common stock is quoted on the OTC Bulletin Board under the symbol UPST.OB. On September 13, 2005, the closing bid price of our common stock as reported on the OTC Bulletin Board was $3.08 per share.

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

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

Prospectus dated , 2005

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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.

Our Business

We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. Affecting urinary or fecal control, voiding dysfunctions debilitate millions of adults worldwide and cost billions of healthcare dollars. Since many of these dysfunctions are highly correlated with age, the aging population will demand increasingly better, and less invasive, solutions for these conditions.

We have developed, and are developing, products primarily for the treatment of urinary and fecal incontinence. Our products offer physicians and patients minimally invasive treatment options. All products we currently market have received CE marking (similar to FDA approval in the U.S.) and are being sold in approximately 40 countries, including in Europe, Canada, Australia and Latin America. Most of our products are not yet cleared for marketing in the United States.

Products we market and have under development include:

Macroplastique® Implants, our key product, is a proprietary, implantable soft tissue bulking product for the treatment of both male and female 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 is also used to treat vesicoureteral reflux, predominately a pediatric condition in which the urine flows backward from the bladder to the kidney. Macroplastique has been sold for urological indications outside the United States since 1991. Our other proprietary, implantable soft tissue bulking agents that we sell outside the United States include PTQ Implants for fecal incontinence, VOX Implants for vocal cord rehabilitation and Bioplastique® Implants for dermal augmentation.

I-Stop tape is a biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. We are the exclusive distributor of this product in the United Kingdom and in the United States. This product recently received premarket clearance for sale within the United States.

The Urgent® PC neuromodulation system is a minimally invasive nerve stimulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. Using percutaneous tibial nerve stimulation, the product delivers an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. In April 2005, we acquired the exclusive rights to manufacture and distribute this product in the United States, Canada and all countries recognizing the CE mark. We do not yet sell the Urgent PC system.

Our goal is to develop and commercialize a portfolio of minimally invasive products for the treatment of voiding dysfunctions. We believe that, with a suite of innovative products, we can increasingly garner the attention of key physicians and distributors and enhance market acceptance of our products. The key elements of our strategy are to:

- Pursue regulatory approval in the United States for our Macroplastique and Urgent PC products;
- Build our own U.S. sales and marketing organization, using a combination of direct and independent reps;
- Expand distribution of our products outside of the United States; and
- Acquire or license complimentary products if appropriate opportunities arise.

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In furtherance of the first key strategy, we are concluding a multi-center human clinical trial with Macroplastique as a minimally invasive, office-based procedure for treating female stress urinary incontinence resulting from internal sphincter deficiency. This is the weakening of the muscles that seal off the flow of urine. In December 2004, the FDA accepted for filing our pre-market approval submission with respect to Macroplastique for the treatment of female stress urinary incontinence. In July 2005, the FDA recommended we conduct further testing of Macroplastique prior to further PMA review and approval. I-Stop recently received 510(k) premarket clearance from the FDA for marketing within the United States. We will be the exclusive distributor of this product in the United States and in the United Kingdom. We are responsible for obtaining and maintaining FDA and foreign regulatory approvals for the Urgent PC system. Although the Urgent PC device currently has received pre-market clearance, in August 2005, we submitted our own 510(k) pre-market notification application for the version of the device we intend to sell.

Our company was incorporated in Minnesota in 1992. Our headquarters are located at 2718 Summer Street N.E., Minneapolis, Minnesota, 55413-2820. Our telephone number is (612) 378-1180. We maintain a web site at 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.

The Offering

Securities offered:	Up to 706,218 shares of common stock upon the exercise of warrants.
Warrants:	
Exercisability	Each warrant is exercisable for one share of common stock.
Exercise period	The warrants are exercisable on or after the date of this Prospectus, and will expire at 5:00 p.m., Minneapolis time, on _____, 2005.
Procedure for exercising warrants	You may exercise all or any portion of your warrants by delivering the following to our principal office at or before 5:00 p.m., Minneapolis time, on the expiration date: your properly completed and signed exercise form; your payment for the total exercise price; and your warrant certificate.
Use of proceeds :	We intend to use the net proceeds from the exercise of the warrants for general working capital purposes.
Common Stock offered by selling shareholder:	100,000 shares of common stock issuable upon the exercise of warrants.
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, you should read the section entitled Risk Factors beginning on page 6.
OTC symbol :	Our common stock is quoted on the OTC Bulletin Board under the symbol UPST.OB.

If all warrants are exercised in connection with our offering, the number of shares of common stock to be outstanding after this offering will equal 7,579,957. This number is based on 6,873,739 shares outstanding as of September 13, 2005, and does not include, as of September 13, 2005, 2,961,787 shares of common stock subject to outstanding options and warrants (including the shares underlying the warrants held by the selling shareholder).

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Summary Financial Data

The following tables present our summary consolidated financial data for our fiscal years ended March 31, 2005 and 2004, which has been derived from our audited consolidated financial statements, and condensed unaudited financial data. The financial data for our three months ended June 30, 2005 and 2004 has 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:

	Three Months Ended June 30,		Fiscal Year Ended March 31,	
	2005	2004	2005	2004
	(unaudited)			
Net sales	$ 1,645,653	$ 1,752,496	$ 6,657,726	$ 5,714,896
Cost of goods sold	420,828	463,558	1,755,456	1,452,331
Gross profit	1,224,825	1,288,938	4,902,270	4,262,565
General and administrative expenses	690,564	391,112	2,260,240	2,069,568
Research and development expenses	630,598	580,053	2,258,127	1,820,690
Selling and marketing expenses	664,033	527,957	2,015,655	1,714,475
Operating loss	(760,370)	(210,184)	(1,631,752)	(1,342,168)
Interest income	27,380	5,879	30,168	30,173
Interest expense	(4,809)	(5,184)	(25,934)	(21,995)
Warrant expense	(686,295)			
Foreign currency exchange gain (loss)	(1,199)	(9,411)	(15,744)	45,882
Other				6,000
Loss before income taxes	(1,425,293)	(218,900)	(1,643,262)	(1,282,108)
Income tax expense	37,020	66,459	91,503	229,185
Net loss	$ (1,462,313)	$ (285,359)	$ (1,734,765)	$ (1,511,293)
Basic and diluted net loss per common share	$ (0.23)	$ (0.06)	$ (0.37)	$ (0.33)
Basic and diluted weighted average common shares	6,351,245	4,591,136	4,651,732	4,517,979

Consolidated Balance Sheet Data:

		March 31,	
	June 30, 2005	2005	2004
	(unaudited)		
Cash and cash equivalents	$ 6,958,238	$ 1,492,684	$ 2,697,670
Working capital	5,843,500	2,374,514	3,671,919
Property, plant and equipment, net	1,077,918	1,040,253	1,071,116
Total assets	10,375,788	4,443,224	5,763,558

Long-term debt, less current portion	419,950	461,265	479,720
Shareholders equity	6,577,226	2,791,896	4,104,233

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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.

Risk Relating to Our Company and Industry

We have incurred significant operating losses and we may not achieve or maintain profitability in the future.

We have incurred net losses in each of the last five fiscal years. As of June 30, 2005, we had an accumulated deficit of approximately $8 million primarily as a result of costs relating to the development and commercialization of our Macroplastique and related products. We expect our operating expenses relating to sales and marketing activities and product development, including seeking U.S. regulatory approvals for Urgent PC and Macroplastique, 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 obtain FDA approval to market the Urgent PC device, Macroplastique, and our ability to achieve widespread market acceptance for those products, which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

If we fail to receive or experience a significant delay in receiving regulatory approvals for sale of our products, our ability to generate revenues will be limited and our business prospects may suffer.

We cannot sell Macroplastique or the Urgent PC device in the United States until we obtain the requisite FDA approvals. If we suffer delays in obtaining or fail to receive regulatory approvals, our ability to generate revenues from the sale of these products will be limited and our future growth may be significantly hampered.

In the United States, we have submitted a pre-market approval submission with respect to Macroplastique. The pre-market approval process is very expensive, uncertain and time-consuming and could materially delay our product coming to market. We cannot predict if or when we will receive pre-market approval for Macroplastique. In July 2005, the FDA recommended we conduct further testing, which we expect will delay possible approval of Macroplastique until late in fiscal 2007. Even if we obtain regulatory approval, it may be only for limited uses with specific classes of patients, which may limit the market for our product.

We believe the Urgent PC nerve stimulation device is eligible for U.S. marketing clearance through the pre-market notification process under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or the FDC Act, based on its substantial equivalence to previously legally marketed devices in the United States. However, we cannot assure you the FDA will agree with our determination that this product is eligible for the Section 510(k) pre-market notification process or that the FDA will not request additional information to support 510(k) clearance. If the FDA requires us to go through a lengthier, more rigorous examination than we expect, our product introductions or modifications could be delayed or canceled, which could adversely affect our sales. We cannot guarantee that the FDA will timely, if at all, clear either of these products for our sale.

To market our products in Europe, they must be approved to affix the CE mark. We cannot assure when, or if, we will be able to obtain our own CE mark approval for the Urgent PC product.

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

We are primarily dependent on sales of our products that contain our Macroplastique bulking agent. Our Macroplastique product line accounted for 76% and 81%, respectively, of total net sales during fiscal 2005 and 2004. If our Macroplastique products were no longer available for sale in any key market because of regulatory, intellectual property or any other reason, our net sales from these products would significantly decline. A significant decline in our net sales could also negatively impact our product development activities and therefore our business prospects.

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We are unable to predict how quickly or how broadly 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.

Even if our products receive 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 assure you that we will be successful in educating the marketplace about the benefits of using our products. Even if customers accept our products, this acceptance may not translate into sales if our competitors have developed similar products that our customers prefer. 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. U.S. and foreign regulations applicable to medical devices are wide-ranging and govern, among other things, the testing, marketing and pre-market review of new medical devices, in addition to regulating manufacturing practices, reporting, advertising, importing, exporting, labeling and record keeping procedures. We are required to obtain regulatory approval or clearance before we can market our products in the United States and certain foreign countries. The regulatory process requires significant time, effort and expenditures to bring our products to market, and we cannot assure that any of our products will be approved 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.

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.

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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.

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 laws of the United States and may not be favorable to us. As a result, we may not be able to compete effectively.

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We also rely on unpatented proprietary technology. We cannot assure you that we can meaningfully protect all of our rights in our unpatented proprietary technology or that others will not independently develop substantially equivalent products or processes or otherwise gain access to our unpatented proprietary technology. We attempt to protect our trade secrets and other unpatented proprietary technology through the use of confidentiality 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 could adversely affect our business and results of operations.

The manufacture and sale of medical devices exposes us to significant risk of product liability claims, some of which may have a negative impact on our business. Our existing products were developed relatively recently and defects or risks that we have not yet identified may give rise to product liability claims. Our existing $2 million of worldwide product liability insurance coverage 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 liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our products, may divert management s attention from other matters and may have a negative impact on our business and our results of operations.

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

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

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

The I-Stop sling is manufactured by CL Medical in France for product distributed by Uroplasty in the UK. For the U.S. market, CL Medical will supply components for I-Stop. CL Medical could experience manufacturing and control problems with its components, and we may not be able to scale-up manufacturing in a timely manner or manufacture sufficient quantities for the U.S. market at a reasonable cost.

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

We currently purchase 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. In fact, one of the suppliers of a component material of our Macroplastique product recently ceased production of this material. Although we have located an alternative supplier, and believe that alternative suppliers for our other materials exist, 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.

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If we or our suppliers are not able to maintain sufficient quality controls, approval of our products by the European Union, the 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 the FDA, European Union or other related authorities if our manufacturing facilities do not comply with applicable manufacturing requirements. The FDA s Quality System Regulations impose extensive testing, control, documentation and other quality assurance procedures. The European Union also imposes requirements on quality 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/or from marketing our products in the United States. We cannot assure you 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 quality system and regulatory requirements. If violations of applicable requirements are noted during periodic inspections of our 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 increase 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 additional sales personnel. We may not be able to attract 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 intend to build our own sales and marketing organization to market our products directly and support our distributor organizations. We will incur significant additional expenses to establish this sales and marketing team. We likely will begin to incur some of these expenses in advance of any anticipated regulatory approval, which we could not recoup if we do not receive such approval. We also may not be able to hire, train and motivate qualified sales and marketing personnel. Failure to expand our distribution and sales channels will adversely affect our sales and revenues.

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® PC technology to us.

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

Even if we complete future acquisitions (including that of CystoMedix, of which there is no assurance), our business, financial condition and the results of operations could be negatively affected because:

- we may be unable to integrate the acquired business successfully and realize anticipated economic, operational and other benefits in a timely manner; and
- the acquisition may disrupt our ongoing business, distract our management and divert our resources.

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

During fiscal 2005, we had two customers that accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% 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 elastomer material in our tissue bulking products and not semi-liquid silicone gel, as was used in breast implants. Negative publicity regarding the use of silicone materials in our products or in other medical devices could have a significant adverse affect on the overall acceptance of our products. We cannot assure you that the use by us and others of solid silicone in implantable 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 all of our net sales from operations in international markets. We expect non-United States sales to continue to represent a substantial portion of our revenues until our products obtain requisite FDA approvals and we achieve sufficient market acceptance from United States customers. The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade regulations. Compliance with such regulations is costly and exposes us to penalties for non-compliance. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our shipping and sales activities.

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

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- political and economic instability;
- fluctuations in the value of the U.S. dollar relative to foreign currencies;
- a shortage of high-quality sales people and distributors;
- loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;

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

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

the imposition of new trade restrictions;

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

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

pricing pressure that we may experience internationally;

laws and business practices favoring local companies;

longer payment cycles;

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

difficulties in enforcing or defending intellectual property rights; and

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

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

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

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

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.

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

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

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

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

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

earthquake, fire, flood and other natural disasters;

terrorist attacks and attacks by computer viruses or hackers; and

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

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

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

Our future success depends, in large part, on the continued service of Sam B. Humphries, our President and Chief Executive Officer. Mr. Humphries continuation with us is integral to our future success, based on his significant expertise and knowledge of our business and products. We have no key person insurance with respect to Mr. Humphries, and any loss or interruption of his services could significantly reduce our ability to effectively manage our operations and implement our strategy. Also, we depend on the continued service of key managerial, scientific, 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 meet our strategic objectives because we cannot assure you 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.

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

Our future liquidity and capital requirements will depend on numerous factors, including:

the timing and cost associated with obtaining FDA approval of Urgent PC and Macroplastique;

the timing and cost involved in manufacturing scale-up and in establishing sales, marketing and distribution capabilities in the U.S. market;

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.

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To the extent that our existing capital is insufficient to meet our working capital needs and cover any losses, we will need to raise additional financing to achieve our business objectives. We currently have no committed sources of, or other arrangements with respect to, additional financing. We cannot assure you that we will be able to obtain additional financing on acceptable terms or at all. Our failure to obtain financing when needed could have a material adverse effect on us. 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.

Risks Relating to this Offering

You may be unable to sell your investment.

There is only a limited trading market for our common stock, which is quoted on the OTC Bulletin Board. Transactions on the OTC Bulletin Board 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.

Further, our common stock is subject to the penny stock rules under the Securities and Exchange Act of 1934. The penny stock rules require brokers who sell penny stocks to persons other than established customers and institutional accredited investors to complete required documentation, make suitability inquiries and provide investors with information concerning the risks of trading in the security. The additional burdens imposed on brokers by these requirements could discourage brokers from effecting transactions in our common stock. Consequently, an investor is likely to find it more difficult to sell 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 FDA approval of our products;

market acceptance of our products;

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

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

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

developments in U.S. or international reimbursement systems;

changes in accounting standards, policies, guidance or interpretations;

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

general economic conditions.

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

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

The market price of our common stock could decline due to sales by our existing shareholders of a large number of shares of our common stock or the perception that these sales could occur. These sales could also make it more difficult for us to raise capital through the sale of common stock at a time and price we deem appropriate. In fact, we currently have an effective registration statement relating to the offer and sale from time to time into the public market by certain of our existing stockholders of 3,328,070 shares of our common stock (including shares underlying warrants owned by such stockholders). In addition, this prospectus covers the issuance of up to 706,218 shares of common stock that existing securityholders may acquire upon the exercise of outstanding warrants, and the offer and sale by a selling shareholder of 100,000 shares of our common stock issuable upon the exercise of warrants. Further, we have also registered 1,051,523 shares of common stock underlying options granted, and which may be granted, under our stock option plans. As of September 13, 2005, 861,259 outstanding options are immediately exercisable.

We will need to monitor and implement finance and accounting systems, procedures and controls as we grow our business and to satisfy new reporting requirements.

In connection with our review of our consolidated financial statements for the year ended March 31, 2005 and the audit of those statements by our independent registered public accounting firm, we determined that our fiscal 2005 year-end closing process did not ensure that all significant elements of our consolidated financial statements were adequately reviewed. In our post-closing and audit processes, certain issues were discovered by us and our independent registered accounting firm that resulted in adjustments to our consolidated financial statements, specifically with respect to our inventory valuation and income tax provision. We discussed these matters before our consolidated financial statements for the year ended March 31, 2005 were completed, and they are properly accounted for in our consolidated financial statements. However, we have concluded that the failure to discover these items in our regular closing process is a result of a significant deficiency, resulting primarily from a lack of segregation of duties due to the size of our company and the geographic distance between our key financial personnel, that constitutes a material weakness in the design or operation of our internal controls over financial reporting.

Although the items described above were properly accounted for before completing our consolidated financial statements, we have concluded that the failure to discover these items in our regular closing process was a material weakness because the elements of our consolidated financial statements that were not adequately reviewed are material to our consolidated financial statements and there is more than a remote likelihood that a material misstatement of our consolidated financial statements would not be prevented or detected.

We have discussed the material weakness described above with our audit committee. Our management is working with our audit committee to identify and implement corrective actions where required to improve the effectiveness of our internal controls, including the enhancement of our systems and procedures. Specifically, we are enhancing and formalizing our period-end closing processes to ensure that all significant elements of our consolidated financial statements are adequately reviewed.

During the fiscal 2004 year end closing process, we determined that our Dutch employee pension plan should have been reported as a defined benefit plan and discovered an error in how we recorded the effect of exchange rates on cash and cash equivalents in our statement of cash flows. As a result, we restated our consolidated financial statements as of and for the fiscal year ended March 31, 2003, and for the first three quarters in fiscal 2004. In connection with our fiscal 2004 audit, our then independent registered public accounting firm cited these restatements as reportable conditions. A reportable condition is a matter that in the independent auditors judgment could adversely affect our ability to process, summarize and report financial data consistent with the assertions of management in our financial statements. To remediate the conditions, our accounting personnel are more carefully reviewing our contracts and agreements and we have a new internal control procedure regarding how we record the effect of exchange rates on our statement of cash flows.

We cannot provide assurance that the measures we have taken to date or any future measures will adequately remediate the deficiencies or conditions discussed above. In addition, we cannot be certain that other reportable conditions or material weaknesses in our internal controls will not be discovered in the future. Any failure to remediate reportable conditions or material weaknesses or to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our

reporting

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obligations, or result in material misstatements in our consolidated financial statements. Any such failure also could adversely affect the results of the periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that will be required when the SEC s rules under Section 404 of the Sarbanes-Oxley Act become applicable to us in April 2006.

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 control systems to allow management to report on, and our independent registered public accounting firm 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, 2007 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 since there is presently no precedent available by which to measure compliance adequacy. 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 exercise our option to acquire the assets of CystoMedix or any other company in the future, we may incur substantial additional costs to bring any acquired company s systems into compliance with Section 404.

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. Currently, we are generally not required to record compensation expense in connection with stock option grants to employees. Because we will be required to expense the fair value of employee stock option grants, it reduces the attractiveness of granting stock options because of the additional expense associated with these grants, which will negatively impact our results of operations. Had we adopted the fair value method for fiscal 2005 and 2004, our net loss would have been $2,321,745 and $253,374, respectively, higher than reported and our net loss per share would have increased $0.50 and $0.06 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. Accordingly, after SFAS 123(R) becomes effective, our results of operations will be negatively impacted if we continue to use stock options as an employee recruitment and retention tool.

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

Provisions in our articles of incorporation may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our articles of incorporation authorize our board of directors to issue up to 20 million shares of stock which, without stockholder 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

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of Section 302A.673, interested shareholder means, generally, someone owning 10% or more of our outstanding voting stock or an affiliate of ours that owned 10% or more of our outstanding voting stock during the past four years, subject to certain exceptions.

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made forward-looking statements in this prospectus. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future financial position, business strategy and plans and objectives for future operations, are forward-looking statements. The words may, will, believe, expect, estima continue, anticipate, 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;

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introduction of competing products;

lack of acceptance of new products;

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

adverse changes in applicable laws or regulations;

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

the failure to integrate effectively newly acquired operations; and

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

We believe that the above factors are important, but not necessarily all of the important, factors that could cause actual results to differ materially from those expressed in any forward-looking statement. Unpredictable or unknown factors could also have material adverse effects on us. Since our actual results, performance or achievements could differ materially from those expressed in, or implied by, the forward-looking statements, we cannot give any assurance that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our 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, amend or clarify these forward-looking statements or the risk factors contained in this prospectus, whether as a result of new information, future events or otherwise, except as may be required under federal securities laws.

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USE OF PROCEEDS

Assuming all warrants are exercised in our offering, we estimate we will receive net proceeds of approximately $1,356,436, after deducting estimated offering expenses payable by us. No underwriting fees or commissions will be payable in connection with this offering. We intend to use the net proceeds of this offering for general working capital purposes.

We will not receive any proceeds from the sale of shares by the selling shareholder.

PRICE RANGE OF COMMON STOCK

The following table sets forth for the period indicated the high and low bid prices for our common stock, as reported by the OTC Bulletin Board (market symbol UPST.OB ; formerly UROP.OB). The last reported bid price per share of our common stock on September 13, 2005, was $3.08. These quotations represent interdealer prices, without retail markup, mark down or commission, and do not necessarily represent actual transactions.

Fiscal Year 2006	**Low Bid**	**High Bid**
April 1 June 30, 2005	$ 3.85	$ 5.00
July 1 August 31, 2005	2.55	6.25

Fiscal Year 2005	**Low Bid**	**High Bid**
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

Fiscal Year 2004	**Low Bid**	**High Bid**
April 1 June 30, 2003	$ 2.07	$ 3.40
July 1 September 30, 2003	2.85	4.40
October 1 December 31, 2003	3.30	5.35
January 1 March 31, 2004	4.05	6.45

As of September 13, 2005, we had approximately 527 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.

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SELECTED FINANCIAL DATA

The following tables present our summary consolidated financial data for our fiscal years ended March 31, 2005 and 2004, which has been derived from our audited consolidated financial statements, and condensed unaudited financial data. The financial data for our three months ended June 30, 2005 and 2004 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:

	Three Months Ended June 30,		Fiscal Year Ended March 31,	
	2005	2004	2005	2004
	(unaudited)			
Net sales	$ 1,645,653	$ 1,752,496	$ 6,657,726	$ 5,714,896
Cost of goods sold	420,828	463,558	1,755,456	1,452,331
Gross profit	1,224,825	1,288,938	4,902,270	4,262,565
General and administrative expenses	690,564	391,112	2,260,240	2,069,568
Research and development expenses	630,598	580,053	2,258,127	1,820,690
Selling and marketing expenses	664,033	527,957	2,015,655	1,714,475
Operating loss	(760,370)	(210,184)	(1,631,752)	(1,342,168)
Interest income	27,380	5,879	30,168	30,173
Interest expense	(4,809)	(5,184)	(25,934)	(21,995)
Warrant expense	(686,295)			
Foreign currency exchange gain (loss)	(1,199)	(9,411)	(15,744)	45,882
Other				6,000
Loss before income taxes	(1,425,293)	(218,900)	(1,643,262)	(1,282,108)
Income tax expense	37,020	66,459	91,503	229,185
Net loss	$ (1,462,313)	$ (285,359)	$ (1,734,765)	$ (1,511,293)
Basic and diluted net loss per common share	$ (0.23)	$ (0.06)	$ (0.37)	$ (0.33)
Basic and diluted weighted average common shares	6,351,245	4,591,136	4,651,732	4,517,979

Consolidated Balance Sheet Data:

		March 31,	
	June 30, 2005	2005	2004
	(unaudited)		
Cash and cash equivalents	$ 6,958,238	$ 1,492,684	$ 2,697,670
Working capital	5,843,500	2,374,514	3,671,919
Property, plant and equipment, net	1,077,918	1,040,253	1,071,116
Total assets	10,375,788	4,443,224	5,763,558

Long-term debt, less current portion	419,950	461,265	479,720
Shareholders equity	6,577,226	2,791,896	4,104,233

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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. We have developed, and are developing, minimally invasive products primarily for the treatment of urinary and fecal incontinence and overactive bladder symptoms. All products we currently sell have received CE marking and are being sold outside the United States in approximately 40 countries, including Europe, Canada, Australia and Latin America.

Our goal is to develop and commercialize a portfolio of minimally invasive products for the treatment of voiding dysfunctions. We believe that, with a suite of innovative products, we can increasingly garner the attention of key physicians and distributors and enhance market acceptance of our products. The key elements of our strategy are to:

Pursue regulatory approval in the U.S. for our Macroplastique and Urgent PC products;

Build our own U.S. marketing and sales organization, using a combination of direct and independent reps;

Expand distribution of our products outside of the U.S.; and

Acquire or license complimentary products if appropriate opportunities arise.

In furtherance of our first key strategy above, we are concluding a multi-center human clinical trial using Macroplastique in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency. This is the weakening of the muscles that control the flow of urine from the bladder. We filed a pre-market approval (PMA) submission with the FDA describing Macroplastique use for this indication. In July 2005, the FDA recommended we conduct further testing, which we expect will delay possible approval of Macroplastique until late fiscal 2007. Although the Urgent PC device currently has U.S. pre-market clearance, in August 2005, we submitted our own 510(k) pre-market notification application for the version of the device we intend to sell. We will incur substantial expense in connection with these regulatory activities.

In the United States, we intend to build our own sales and marketing organization to market our products directly and support our distributor organizations. We will incur significant additional expenses to establish this sales and marketing team. We likely will begin to incur some of these expenses in advance of any anticipated regulatory approval, which we could not recoup if we do not receive such approval.

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. We market and distribute our products through a network of distributors and through direct sales to end-users in the United Kingdom and The Netherlands. 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 the Uroplasty 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 are estimated not to be substantially different than our sales to those distributors in each of the last two years. Our distributors level of inventories of our products, their sales to end-user customers and their internal product requirements may impact our future revenue growth.

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

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

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

Impairment of Long-Lived Assets. Long-lived assets at June 30, 2005 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.

Results of Operations

Three-months ended June 30, 2005 and 2004

Net Sales. In the first quarter ended June 30, 2005, net sales of all products were $1.6 million, representing a $107,000 or 6% decrease when compared to net sales of $1.8 million for the quarter ended June 30, 2004. Excluding fluctuations in foreign currency exchange rates, we had a sales decrease of approximately 10%. The Macroplastique product line accounted for 70% and 79% of total net sales, respectively, for the first quarter of fiscal 2006 and 2005. Two of our top six distributor markets generated minimal sales in the quarter ended June 30, 2005, due in part to reimbursement changes which we expect to adversely impact our future sales in those markets. Additionally, the sling adoption rate for converting physician use of competitive sling devices to our I-Stop product in the United Kingdom was below our forecast. In those markets affected by reimbursement issues, and in the United Kingdom, we have launched a two-fold strategy to increase sales of our products. First, we are conducting workshops targeted to key incontinence surgeons. Second, we are seeking to broaden our patient base to include treatments for fecal incontinence

and overactive bladder, which we will support with our platform of new products.

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Gross Profit. Gross profit was $1.2 million and $1.3 million for the quarters ended June 30, 2005 and 2004, respectively, or 74% of net sales in both periods. Gross profit as a percentage of net sales in any one specific period may fluctuate, 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 foreign currency fluctuations. Historically, the gross margin has ranged from approximately 70-80% of net sales.

General and Administrative Expenses. General and administrative (G&A) expenses increased from $391,000 during the first quarter of fiscal 2005 to $691,000 during the first quarter of fiscal 2006. The G&A expense increase related to increased salary costs of $160,000, a $65,000 increase in accounting and legal professional fees, a $70,000 information technology (IT) consulting expense, and general price increases and fluctuations in foreign currency exchange rates. The increased salary cost relates to added personnel. The IT consulting expense relates to the expected implementation of a new computer software system.

Research and Development Expenses. Research and development (R&D) expenses increased from $580,000 during the first quarter of fiscal 2005 to $631,000 during the first quarter of fiscal 2006. The increase in R&D expense is due to added personnel, general price increases and fluctuations in foreign currency exchange rates.

Selling and Marketing Expenses. Selling and marketing (S&M) expenses increased from $528,000 during the first quarter of fiscal 2005 to $664,000 during the first quarter of fiscal 2006. The increase resulted from an $85,000 increase in personnel costs, increase in travel expenses, increased costs relating to trade-shows, conventions and congresses, and general price increases and fluctuations in foreign currency exchange rates. The increased personnel cost relates to added personnel.

Other Income (Expense). Other income (expense) includes interest income, interest expense, warrants expense, 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 expense was $665,000 and $8,700 for the first quarters ended June 30, 2005 and 2004, 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 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 this registration statement covering the shares underlying these warrants. In April 2005, we recognized a liability of $1.4 million associated with the grant of these warrants. The value of these warrants has been determined using the Black-Scholes option-pricing model. We reported expense of approximately $686,000 in the first quarter due to the increase in the fair value of these warrants from their date of issue through June 30, 2005. This fair value adjustment for each warrant will be continued until such time as the warrant is exercised or expires.

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 $1,200 and $9,400 for the first quarters ended June 30, 2005 and 2004, respectively.

Income Tax Expense: Our Dutch subsidiaries recorded income tax expense of $37,000 and $66,000 for the quarters ended June 30, 2005 and 2004, respectively, as they have fully utilized their net operating loss carryforwards. We cannot use the U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions. We expect continued profits for our Dutch subsidiaries and therefore continued income tax expenses. Effective January 1, 2005, the Dutch income tax rate dropped to 27% for 22,689 (approximately $27,000) of profit and 31.5% for amounts above 22,689 from 29% and 34.5% in 2004.

Years Ended March 31, 2005 and 2004

Net Sales. In fiscal 2005, net sales of all products were $6.7 million, representing a 16% increase when compared to net sales of $5.7 million for fiscal 2004. Excluding fluctuations in foreign currency exchange rates, we had a sales

increase of approximately 8%. The net sales increase is partly contributed by price increases, but mainly attributable by increased unit sales. We believe the continued increase in net sales is related to the impact and execution of sales plans designed to expand our global market share in the specialties of both urinary and fecal incontinence. The Macroplastique product line accounts for 76% and 81% of total net sales, respectively, during the periods presented. We also depend on

key customers. During fiscal 2005, two customers accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% and 11% of our net sales.

Gross Profit. Gross profit was $4.9 million and $4.3 million for the fiscal years ended March 31, 2005 and 2004, respectively, or 74% and 75% of net sales. Gross profit as a percentage of net sales in any one specific period may fluctuate, 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, the gross margin has ranged from approximately 70-80% of net sales. This primarily relates to our Macroplastique products.

General and Administrative Expenses. General and administrative (G&A) expenses increased from $2.1 million during fiscal 2004 to $2.3 million during fiscal 2005. The G&A expense increase related to increases of $231,000 in personnel costs due to additional staff and increased salaries, a $217,000 increase in professional fees for accounting and legal services, an increase of $187,000 in bad debt expense, mainly to reserve for a receivable of one of our distributors, general price increases and fluctuations in foreign currency exchange rates. This increase was offset by decreased consulting expenses of $135,000 and decreased shareholders expenses of $349,000. The decrease in both the consulting fees and the shareholders expenses primarily relates to $473,000 of stock-based compensation expense we recognized in fiscal 2004.

Research and Development Expenses. Research and development (R&D) expenses increased 24% from $1.8 million during fiscal 2004 to $2.3 million during fiscal 2005. The increase in R&D expense is primarily due to quality and regulatory costs related to the development of our pre-market approval submission for U.S. market clearance for Macroplastique in the treatment of adult female stress urinary incontinence. In July 2005, the FDA recommended we conduct further testing of Macroplastique, which we expect will further increase our R&D expenses.

Selling and Marketing Expenses. Selling and marketing (S&M) expenses increased 18% from $1.7 million during fiscal 2004 to $2.0 million during fiscal 2005. This increase resulted from a $210,000 increase in personnel costs, an additional $164,000 in costs relating to trade-shows, conventions and congresses, general price increases, and fluctuations in foreign currency exchange rates. The increase was offset by a decrease in promotional costs of $73,000. The increased personnel costs relate to the hiring of experienced sales personnel and increased salaries and bonuses.

Other Income (Expense). Other income (expense) includes interest income, interest expense, foreign currency exchange gains and losses, and other non-operating costs when incurred. Other income (expense) was $(12,000) and $60,000 for the fiscal years ended March 31, 2005 and 2004, respectively. We recognize exchange gains and losses primarily as a result of fluctuations in currency rates between the U.S. dollar (the functional reporting currency) and the euro and British pound (currencies of our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between us and our foreign subsidiaries. We recognized foreign currency gains (losses) of $(16,000) and $46,000 for the periods presented. We cannot predict the impact of currency fluctuations on our future results.

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 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 this registration statement covering the shares underlying these warrants. In April 2005, we recognized a liability of $1.4 million associated with the grant of these new warrants. The value of these warrants has been determined using the Black-Scholes option-pricing model and we will continue to report in earnings any subsequent change in the fair value of this liability.

Income Tax Expense. Our Dutch subsidiaries recorded income tax expense of $92,000 and $229,000 for the periods presented, as they have fully utilized their net operating loss carryforwards. We cannot use our U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions. We expect continued profits for our Dutch subsidiaries

and therefore continued income tax expenses. For fiscal 2005, the Dutch income tax rate was 29% for the first (approximately $29,000) of profit and 34.5% thereafter. 22,689

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Liquidity and Capital Resources

Cash Flows. As of June 30, 2005, our cash and cash equivalent balances totaled $7.0 million.

At June 30, 2005, we had working capital of approximately $5.8 million. During the first quarter of fiscal 2006, we used $900,000 of cash in operating activities, compared to $200,000 of cash used in the first quarter of fiscal 2005. The usage of cash was primarily attributable to the net loss incurred of $1,500,000 (adjustments to reconcile net loss to net cash used in operating activities totaled $750,000). Inventory increased by $200,000, due to production planning requirements and manufacturing lead times. Accounts receivable, other current assets, accounts payable and accrued expenses fluctuated due to the timing of payments and fluctuations in foreign currency exchange rates.

Our financial condition and results of operations could be materially affected by fluctuations in foreign currency exchange rates and weak economic conditions in foreign markets where we sell and distribute our products. The effects of these conditions could include reduced unit sales and reduced sales in dollars when converted from foreign currency amounts and material gains and losses on transactions denominated in foreign currencies. Furthermore, because our U.S. operations are funded by sales denominated in foreign currency, strengthening of the U.S. dollar against the euro, and/or the British pound could have an adverse effect on our cash flow and results of operations.

Sources of Liquidity. In March 2005, we entered into a business loan agreement with Venture Bank, pursuant to which we may borrow up to $500,000 on a revolving basis. All amounts which the bank advances to us are due in March 2006, unless the bank renews the agreement. Amounts advanced to us accrue interest at a variable rate of 1% in excess of the published prime rate in the Wall Street Journal, with a minimum rate of 6% per annum. We are obligated to pay interest monthly on the outstanding principal balance. Advances under this agreement are secured by substantially all our assets. At June 30, 2005 we had no outstanding balance under the agreement.

In April 2005, we conducted a private placement of common stock 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 common stock, for an aggregate purchase price of approximately $7.5 million. These proceeds were offset by costs of approximately $700,000, resulting in net proceeds of approximately $6.8 million. The warrants are exercisable for five years at an exercise price of $4.75 per share.

In connection with our April 2005 private placement, we agreed to file a registration statement with the SEC covering the resale of the shares (including those underlying the warrants) that we sold. We also agreed that, for each month after May 21, 2005, that we failed to file this registration statement, and for each month after July 20, 2005 that the SEC did not declare it effective, we would pay liquidated damages at a rate of 1% of the aggregate investment. We filed the registration statement on July 20, 2005 and the SEC declared it effective on July 29, 2005. Accordingly, we owe approximately $148,500 of liquidated damages to the investors, which will continue to accrue interest at 10% per annum until paid. We intend to seek a waiver from the investors of these liquidated damages, but we cannot assure that all or any of the investors will grant us this waiver. We recorded a liability in our financial statements beginning in the first quarter of fiscal 2006 related to these liquidated damages.

Commitments and Contingencies. We believe that our current resources, funds generated from sale of our products outside the U.S., along with existing bank arrangements and the proceeds received from the recently completed private placement will be adequate to meet our cash flow needs, including regulatory activities associated with existing products, through fiscal 2006. Ultimately, we will need to achieve profitability and positive cash flows from operations to fund our operations and grow our business beyond fiscal 2006.

We expect to continue to incur significant costs for regulatory activities associated with obtaining regulatory approval in the United States for Macroplastique and the Urgent PC device. For fiscal 2006, we have budgeted approximately $4.2 million for our R&D expenses, including those we expect to incur in connection with the additional testing on Macroplastique recently recommended by the FDA. We also expect that during fiscal 2006, our selling and marketing expenses will increase as we prepare for the initial U.S. marketing of our products. In addition, we currently expect general and administrative expenses in fiscal 2006 to increase as we prepare to implement the provisions of Section 404 of the Sarbanes-Oxley Act of 2002.

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix for the Urgent PC product. We paid CystoMedix an initial royalty payment of $225,000 which has been capitalized as licensed technology and will be amortized over the term of the agreement. Also, we are paying an additional $250,000 in

12 monthly installments of $20,833. We will also pay CystoMedix a 7% royalty on product sales. However, the 7% royalty is first offset against the monthly royalty installments.

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CystoMedix has also granted us an exclusive option to acquire its 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. We may exercise the option between January 2006 and 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. Depending on our available cash, we might need to raise additional equity or debt funds in order to consummate the CystoMedix acquisition, should we elect to do so.
We are obligated to pay royalties of 5% of net sales in the U.S. of Macroplastique products with a minimum of $50,000 per year. The duration of this royalty agreement is through 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 16 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. This defined benefit plan is closed for new employees effective April 2005. As of that date, the Dutch subsidiary established a 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.
Under our agreement with CL Medical for the I-Stop product, we have agreed to purchase our entire requirement of product components from CL Medical. We have a specified minimum purchase requirement of $240,000 of units in the first year after FDA clearance, increasing to approximately $1.9 million of units over a five-year period subject to periodic adjustment based on the value of the euro.
Repayments of our contractual obligations, consisting of royalties, notes payable, and operating leases, are summarized below:

		Payments Due by Period		
	Total	Remainder of Fiscal 2006	Fiscal 2007	Fiscal 2008 and thereafter
Minimum royalty payments	$ 546,333	$ 228,000	$ 124,833	$ 193,500
Notes payable	461,565	31,204	41,605	388,756
Operating lease commitments	356,805	228,900	96,490	31,415
Total contractual obligations	$ 1,364,703	$ 488,104	$ 262,928	$ 613,671

Recent Accounting Pronouncements
In May 2005, the FASB issued FASB Statement No. 154, *Accounting Changes and Error Corrections*. This new standard replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements*. Among other changes, Statement 154 requires retrospective application of a voluntary change in accounting principle with all prior period financial statements presented on the new accounting principle, unless it is impracticable to do so. Statement 154 also requires accounting for a change in method of depreciating or amortizing a long-lived nonfinancial asset as a change in estimate (prospectively) effected by a change in

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accounting principle. Further, the Statement requires that correction 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 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 FASB Statement 154 will have a material effect on our financial position or results of operations.

In December 2004, the FASB issued SFAS 123(R), *Share-Based Payment*, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation,* and supersedes APB Opinion 25, *Accounting for Stock Issued to Employees.* SFAS 123(R) 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) is effective for us beginning on April 1, 2006. We expect the provisions of SFAS 123(R) to result in a significant charge to compensation expense, as we currently do not recognize stock compensation expense in accordance with SFAS 123(R).

In March 2005, the FASB issued FASB Interpretation No.47, or FIN 47, which clarifies terminology in FASB Statement No. 143, *Accounting for Asset Retirement Obligations*. FIN 47 clarifies when an entity has sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 is effective for us in fiscal 2006. We do not expect adoption of FIN 47 to 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. Affecting urinary or fecal control, voiding dysfunctions debilitate millions of adults worldwide and cost billions of healthcare dollars. Since many of these dysfunctions are highly correlated with age, the aging population will demand increasingly better, and less invasive, solutions for these conditions.

We have developed, and are developing, minimally invasive products primarily for the treatment of urinary and fecal incontinence and overactive bladder symptoms. All products we currently sell have received CE marking and are being sold outside the United States in approximately 40 countries, including Europe, Canada, Australia and Latin America. Products we market and have under development include our Macroplastique urethral bulking agent, the I-Stop tape and the Urgent PC neurostimulation system.

Macroplastique Implants, our key product, is a proprietary, implantable soft tissue bulking product for the treatment of both male and female 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 is also used to treat vesicoureteral reflux, predominately a pediatric condition in which urine flows backward from the bladder to the kidney. Macroplastique has been sold for urological indications outside the United States since 1991. Our other proprietary, implantable soft tissue bulking agents that we sell outside the United States include PTQ Implants for fecal incontinence, VOX Implants for vocal cord rehabilitation and Bioplastique Implants for dermal augmentation.

I-Stop is a biocompatible, polypropylene, tension-free sling for the treatment of female urinary incontinence. We are the exclusive distributor of this product in the United Kingdom and in the United States. This product recently received premarket clearance from the FDA for sale within the United States.

The Urgent PC neuromodulation system is a minimally invasive neuromodulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. Using percutaneous tibial nerve stimulation, the product delivers an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. In April 2005, we acquired the exclusive rights to manufacture and distribute this product in the United States, Canada and all countries recognizing the CE mark. We do not yet sell the Urgent PC system.

Our goal is to develop and commercialize a portfolio of minimally invasive products for the treatment of voiding dysfunctions. We believe that, with a suite of innovative products, we can increasingly garner the attention of key physicians and distributors and enhance market acceptance of our products. The key elements of our strategy are to:

Pursue regulatory approval in the United States for our Macroplastique and Urgent PC products.

Build our own U.S. marketing and sales organization, using a combination of direct and independent reps;

Expand distribution of our products outside of the United States; and

Acquire or license complimentary products if appropriate opportunities arise.

In furtherance of our first key strategy above, we are concluding a multi-center human clinical trial using Macroplastique in a minimally invasive, office-based procedure for treating adult female stress urinary incontinence resulting from intrinsic sphincter deficiency. This is the weakening of the muscles that control the flow of urine from the bladder. We recently filed a pre-market approval submission with the FDA describing Macroplastique use for this indication. In July 2005, the FDA recommended we conduct further testing prior to further PMA review and approval. I-Stop recently received 510(k) pre-market clearance from the FDA for marketing within the United States. Although the Urgent PC device currently has U.S. pre-market clearance, in August 2005, we submitted our own 510(k) pre-market notification application for the version of the device we intend to sell.

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Voiding Dysfunctions

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

The Problem of Urinary Incontinence

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

Causes of Urinary Incontinence

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

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

Types of Urinary Incontinence

There are four types of urinary incontinence:

Stress Urinary Incontinence - Stress urinary incontinence, 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 U.S.), their incontinence is caused by urethral hypermobility. Urethral hypermobility abnormal movement of the bladder neck and urethra occurs when the anatomic supports for the bladder neck and urethra have weakened. This anatomical change is often the result of childbirth. Stress urinary incontinence can also be caused by intrinsic sphincter deficiency, or the inability of the sphincter 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. The National Association for Continence (NAFC) estimates up to 15% of female stress urinary incontinence is a result of ISD. For many women, their SUI is a combination of urethral hypermobility and ISD.

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

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

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

Management and Curative Treatment of Urinary Incontinence

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

Management of Urinary Incontinence

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

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

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

Urinary Catheters and Collection Devices. The type and severity of incontinence and an individual s physical and mental condition determine the choice of catheter. Catheters may be inserted as needed for bladder drainage, 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. Active women benefit from the use of urethral bulking agents since they will often return to normal activities in a matter of days instead of weeks of recovery following invasive surgical procedures. Bulking agents also represent a desirable treatment option for the elderly or infirm who may not otherwise be able to withstand the trauma and morbidity resulting from a fully invasive surgical procedure. Additionally, the use of a urethral bulking agent does not preclude the use of more invasive treatments if required.

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

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

Surgery. In women, stress urinary incontinence can be surgically corrected through a procedure in which the physician elevates and stabilizes the urethra and bladder neck, often with a sling to support these structures. Market adoption of sling procedures is demonstrated by over 10% annual growth during the last five years. An estimated 180,000 sling procedures will be performed in the United States during 2005, with almost half of these procedures using a tension-free sling product, usually implanted in an outpatient setting. Numerous publications cite sling procedure efficacy greater than 85%.

In men, the main surgical option is an implanted artificial urinary sphincter, a patient-controlled device that keeps the urethra closed until the patient is ready to urinate. Surgery to place the artificial sphincter requires general or spinal anesthesia.

Uroplasty Solutions for Urinary Incontinence

We believe that we are uniquely positioned with differentiable, minimally invasive products to address both causes of SUI an injectable bulking agent to treat ISD and a tension-free type sling to treat urethral hypermobility.

Macroplastique® Implants

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 50,000 patients treated. Recently, we filed a pre-market approval submission with the FDA for domestic marketing of Macroplastique for the treatment of adult female stress incontinence. In July 2005, the FDA recommended we conduct further testing, which we expect will delay possible approval of Macroplastique until late fiscal 2007.

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 , 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.

I-Stop Sling

In May 2004, we became the exclusive distributor in the United Kingdom of the I-Stop tape, a biocompatible, tension-free, mid-urethral sling manufactured by CL Medical SAS of Lyon, France. This CE marked device, which is sold in Europe, is for the treatment of female urinary incontinence due to urethral hypermobility. If the urethra is no longer appropriately supported by the surrounding tissues and ligaments, the urethra may become too moveable and no longer properly close. A sling provides a hammock-type support for the urethra to prevent its downward movement, and associated leakage of urine, during periods of increased abdominal pressure.

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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. For patients, we believe that our tape design results in less irritation and fewer overall complications.

In September 2004, we entered into an exclusive manufacturing and distribution agreement with CL Medical under which we have expanded our relationship to become the exclusive distributor of the I-Stop sling in the United States. The I-Stop product is approved by the FDA for sale in the United States. We are responsible for FDA regulatory requirements for I-Stop manufacturing, including processing, assembly, sterilization, packaging and labeling of the product for the U.S. market. The manufacturing and distribution agreement is for six years, with our right to renew it for successive five-year terms. We have agreed to purchase our entire requirement of product components from CL Medical. We have a specified minimum purchase requirement of $240,000 of units in the first year after FDA clearance, increasing to approximately $1.9 million of units over a five-year period, subject to periodic adjustment based on the value of the euro. CL Medical will provide us with any improvements it makes to the I-Stop sling without additional charge. In addition, CL Medical has granted us a right of first refusal for exclusive manufacturing, assembly and/or distribution rights in the United States to any new medical devices or procedures it develops during the term of our agreement. In return, we have agreed that during, and for three years 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.

The Problem of Overactive Bladder

Overactive bladder (OAB) is a prevalent and challenging urologic problem affecting 16% of the adult population. An estimated 34 million Americans suffer from overactive bladder, although fewer than 40% seek medical help. A survey of individuals with OAB estimated the total U.S. economic cost of OAB (direct and indirect costs) to be $12 billion. For individuals with overactive bladder, the nervous system control for bladder filling and urinary voiding is incompetent. Signals to indicate a full bladder are sent early and frequently, triggers to allow the bladder to relax for filling are ineffective and nervous control of the urethral sphincter, to keep the bladder closed until an appropriate time, is inadequate. An individual with OAB may exhibit one or all of the symptoms that characterize overactive bladder: urinary urgency, urinary frequency and urge incontinence. Urgency is the strong, compelling need to urinate. Frequency is a repetitive need to void. Normal urinary voiding is eight times per day. Individuals with an overactive bladder may seek to void over 20 times per day and at least two times during the night, thereby causing significant sleep pattern disturbances. Urge incontinence is an immediate, compelling need to urinate that typically results in an accident before the individual can reach the restroom.

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 headache.

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.

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The sacral nerve stimulator uses a small device, a neurostimulator, to send mild electrical pulses to the sacral nerve. The sacral nerve is located in the lower back, just above the tailbone. The surgically implanted neurostimulator contains a battery and electronics to create the electrical pulses and is connected to a neurostimulation lead (an insulated wire) containing electrodes through which stimulation is delivered to the nerve. The device is most frequently placed under the skin of the buttock, with the lead under the skin near the spine.

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

Urgent® PC Neuromodulation System

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 U.S., Canada and all countries recognizing the CE mark. 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 U.S. market for treatment of overactive bladder symptoms. Components of the Urgent PC system include a hair-width needle electrode, a lead set and an external, handheld, battery-powered stimulator. For each 30-minute office-based therapeutic session, the physician temporarily inserts the needle electrode in the patient s lower leg and connects the electrode to the stimulator. Typically, a patient undergoes 12 treatment sessions at one-week intervals, with followup treatments as required to maintain symptom reduction.

CystoMedix obtained approval to affix the CE mark on the Urgent PC device and began marketing it in Europe during 2003. The Urgent PC is also cleared for sale in the United States. Under our agreement with CystoMedix, we are responsible for regulatory applications and compliance within all markets outlined in the agreement. We plan to seek our own CE mark approval. Although the Urgent PC currently has U.S. pre-market clearance, in August 2005 we submitted to the FDA our own 510(k) application for the version of the device we intend to sell.

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 are paying 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.

The Problem of Fecal Incontinence

Fecal incontinence is an extremely disabling and embarrassing condition. Its prevalence is 2-6% of the adult population, with women suffering from fecal incontinence up to four times more often than men. Approximately 25%

of women with stress urinary incontinence are also diagnosed with fecal incontinence.

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

Treatment of Fecal Incontinence

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

Uroplasty Solutions for Fecal Incontinence

We have, 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.

Other Uroplasty Products

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

In The Netherlands and United Kingdom only, we distribute certain wound care products in accordance with a 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 market and sell Macroplastique and related ancillary products, and the I-Stop sling, only in countries outside the United States. We have a direct sales force in the United Kingdom. International sales managers in The Netherlands manage and train a network of distributors selling our Macroplastique and related products in approximately 40 countries, including Canada, Australia, countries within Europe and Latin America, and the I-Stop sling in the United Kingdom. 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 70% and 66% of total net sales for fiscal 2005 and 2004, respectively. As the FDA approves our products, we will expand our sales and marketing organization to support sales in the United States. Recently, I-Stop received FDA clearance and we are now initiating our first U.S. market launch.

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/or 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 and on the Macroplastique Sling Support Kit (MIS-SK). 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.

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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.

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 facilities and systems were last audited by AMTAC Certification Services in January 2005. 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, we will also be inspected by the FDA for compliance with U.S. federal Quality System Regulations and will be subject to additional state, local, and federal government regulations applicable to the manufacture of our products.

CL Medical in Lyon, France manufactures the I-Stop sling. Pursuant to the manufacturing and distribution agreement with CL Medical, we are required to purchase all of our product component requirements from CL Medical. We have specified minimum purchase requirements of $240,000 of units in the first year after FDA clearance of I-Stop, increasing to approximately $1.9 million of units over a five-year period, subject to periodic adjustment based on the value of the euro. We are required to establish our own manufacturing facility or to outsource to a third party the assembly of the final product and sterilization, packaging and labeling of the finished product. 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 will be responsible for establishing our own manufacturing facility or for subcontracting the manufacture of the Urgent PC device. We currently expect to 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 competitive factors among treatment methods include physician and patient acceptance of the method in managing or curing incontinence, cost and 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® (not FDA approved) 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 System offers a unique, non-endoscopic, minimally invasive outpatient procedure that can be performed in the physician s office.

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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 Mentor Corporation. We believe the I-Stop sling offers benefits of multiple surgical approaches for the physician and a design to resist stretching, deformity (i.e., preventing the cord effect) and fragmentation.

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

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

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, or total or partial suspension of production;
- denial of requests for 510(k) clearance or pre-market approval of new products;
- withdrawal of existing approvals; and
- criminal prosecution.

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

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The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

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

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

Pre-market Approval. A pre-market approval (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 the 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 the FDA determines that a PMA submission is complete, the FDA accepts the submission and begins an in-depth review of the submitted information. The 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, the FDA may request additional information, testing or clarification of information already provided. Also during this review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct clinical inspections at investigational sites and a pre-approval inspection of the manufacturing facility to ensure compliance with the U.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;

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

notices of correction or removal, and recall regulations.

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FDA Approval Status of Our Products. The 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, the FDA approved our IDE application with respect to Macroplastique for the treatment of stress urinary incontinence. In 2000, we commenced a human clinical trial at multiple sites. We have concluded the 12-month patient follow up visits for this study, recently submitted a PMA submission with respect to Macroplastique and will be submitting final 24-month follow up visits on Macroplastique patients. In July 2005, the FDA recommended we conduct further testing, which we expect will delay possible approval of Macroplastique until late fiscal 2007.

The Urgent PC device previously received 510(k) clearance for U.S. marketing by the FDA. However, we submitted our own 510(k) pre-market application in August 2005 for the version of the product that we intend to sell in the United States. We cannot guarantee that the FDA will agree with our view that the Urgent PC is eligible to use the 510(k) clearance process or that the FDA will not request additional information to support 510(k) clearance. A not substantially equivalent determination or request for additional data could prevent or delay the market introduction of the Urgent PC, which in turn could have a material adverse effect on our potential revenues.

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

- regulate our design and manufacturing processes and control them by the use of written procedures;
- investigate any deficiencies in our manufacturing process or in the products we produce;
- keep detailed records and maintain a corrective and preventative action plan; and
- allow the FDA to inspect our manufacturing facilities on a periodic basis to monitor our compliance with Quality System Regulations.

Although 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, they have not been inspected by the FDA for compliance with Quality System Regulations. We cannot assure 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 the 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 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 received CE marking approval in July 2002. CystoMedix, the company that granted us rights to manufacture and distribute the Urgent PC nerve stimulation device, also obtained its own CE mark. As we transition this product to our company, we anticipate applying for our own CE mark approval for the Urgent PC device.

We currently sell our products in about 40 foreign countries, including those within the European Union. Requirements pertaining to medical devices vary widely from country to country, ranging from no health regulations to detailed submissions such as those required by the FDA. We 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.

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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.

We believe that coding, coverage and payment issues for tension-free sling products have been addressed by numerous competitors. However, we will need to determine if reimbursement for the I-Stop product will require any modifications of coding, coverage or payment policies. It appears that appropriate codes are available to describe endoscopic use of Macroplastique to treat female SUI, but coding will need to be confirmed. We expect that, upon FDA approval to market Macroplastique, we will need to foster coverage policies and payer acceptance to support the U.S. launch. As a relatively new therapy, PTNS using the Urgent PC is not adequately described by existing codes. We will need to provide customer reimbursement support during our launch and early growth, seek coverage policies, secure market acceptance and support advocacy to secure new coding for this procedure. There is no uniform policy for reimbursement throughout the United States and no guarantee Macroplastique, the I-Stop sling or the Urgent PC device 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 U.S. and foreign patents of ours will not be challenged, narrowed, invalidated or circumvented by competitors or others, or that our patents will provide us with any competitive advantage. Any legal proceedings to maintain, defend or enforce our patent rights could be lengthy and costly, with no guarantee of success. CystoMedix and CL Medical also have certain patent rights which they licensed to us as part of their respective manufacturing and distribution agreements.

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

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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 three to five percent of net sales of Macroplastique and Bioplastique, subject to a monthly minimum of $4,500. The royalties payable under this agreement will continue until the patent referenced in the agreement expires in 2010.

In October 1998, we received an absolute assignment from a British surgeon of a patent relating to the Macroplastique Implantation System in return for a royalty of £10 for each unit sold during the life of the patent. We began commercialization of the product outside the United States in March 2000.

Research and Development

We have a research and development program to develop new incontinence products. We are also continually evaluating potential improvements as well as new methods and devices for the implantation of Macroplastique and on new applications for this material. Research and development expenses also include the costs of clinical studies and regulatory compliance. Our expenditures for research and development totaled $2.3 and $1.8 million for fiscal 2005 and 2004, respectively. None of these costs were borne directly by customers.

Product Liability

The medical device industry is subject to substantial litigation. As a manufacturer of a long-term implantable device, we face an inherent risk of liability for claims alleging adverse effects to the patient. We currently carry $2 million of worldwide product liability insurance, 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 2005 and 2004 has not had a material effect upon our capital expenditures, earnings or competitive position.

Dependence on Major Customers

During fiscal 2005, two customers accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% and 11% of our net sales.

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Employees

As of August 26, 2005, we had 52 employees, of which 42 were full-time and 10 were part-time. No employee has a collective bargaining agreement with us. We believe we maintain good relations with our employees.

Properties

We own 9,774 square feet of office and warehouse space in Geleen, The Netherlands. In addition, we lease 13,705 square feet of office, warehouse, laboratory and production space through February 2006 in Minneapolis, Minnesota, which serves as our corporate office. We further lease 5,230 square feet of office and warehouse space through September 2011 (subject to our right to terminate early starting in 2006) in Reading, United Kingdom and 2,330 square feet of office, warehouse, laboratory and manufacturing space through June 2007 in Eindhoven, The Netherlands.

We believe our facilities are currently adequate to meet our needs. However, we may need additional office, production and warehouse space upon FDA approval of our products and subsequent increases in production, marketing and sales activities in the U.S.

Legal Proceedings

On July 15, 2005, our former Vice President of Research and Development and Managing Director of our United Kingdom subsidiary, filed a petition in Dutch Court (Roermond). The petition requests the Dutch court to terminate his employment agreement with us and made a claim for 528,058 (or approximately $636,000) in severance compensation as well as other damages. We opposed the petition and sought to pay no more than approximately $100,000 in total severance compensation under the employment agreement. In August 2005, the Dutch Court granted a total award to the former employee of 177,000 (or approximately $219,000). We do not plan to appeal this determination and will record the liability and related expense in the second quarter of fiscal 2006.

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MANAGEMENT

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

Name	Age	Position
Daniel G. Holman	59	Chairman and CFO
Sam B. Humphries	63	President, CEO and Director
Joel R. Pitlor	66	Director
R. Patrick Maxwell	60	Director
Thomas E. Jamison	45	Director
Susan Hartjes Holman	51	COO and Secretary
Larry Heinemann	52	Vice President Sales & Marketing
Arie J. Koole	41	Controller Managing Director Dutch subsidiaries
Marc M. Herregraven	40	Vice President of Manufacturing

Daniel G. Holman has served as Chairman of our Board since February 1994 and as our Chief Financial Officer since February 2001. He served as our President and Chief Executive Officer From February 1994 to December 2004, and as our Chief Financial Officer from June 1996 to November 1999. He was Executive Vice President of Bioplasty, Inc. (our former parent) from 1973 to 1985, its President from 1985 to 1987, and Secretary from 1986 to March 1992. Mr. Holman was Chairman of the Board of Bioplasty, Inc. from March 1992, and President and CEO from February 1993 to December 2001. He served as Chairman of the Board and Chief Executive Officer of Bio-Vascular, Inc. from June 1988 to September 1991 and served as a director of Genetic Laboratories Wound Care, Inc. from February 1988 until July 1993, and as Vice President from February 1988 through November 1992. Mr. Holman holds a B.A. in Biology from St. Cloud State University.

Sam B. Humphries has served as our President and Chief Executive Officer since January 2005 and as a director since April 2003. He has more than 25 years of healthcare and medical device industry experience. Most recently, he was a founding partner of Ascent Medical Technology Fund L.P., a venture capital fund. Prior to that, Mr. Humphries was President and Chief Executive Officer of American Medical Systems, Inc., where he was an investor and part of a leveraged buy out group (spin-off) from Pfizer. Before joining AMS, Mr. Humphries was President and Chief Executive Officer of Optical Sensors, Inc., a medical start-up company he guided from start-up through its initial public offering. Prior to OSI, Mr. Humphries was with AMS during its formative years where he first served as Vice President of World Wide Sales and Marketing and then as President and Chief Executive Officer. Earlier, he served in several management positions with the Medical Systems Group of General Electric Company. Mr. Humphries has also served as a director of numerous private and public companies, including as director of Health Industry Manufacturers Association (HIMA, now AdvaMed), Inlet Medical, Inc., Universal Hospital Services, Inc. and the Ascent Medical Technology Fund.

Joel R. Pitlor became a director of our company in February 1994. He served as a director of Bioplasty, Inc. from January 1989 until May 1996. For over sixteen years, he has been the owner and manager of a management consulting firm. Mr. Pitlor is presently a director of Precision Optics Corporation, which is publicly held. Mr. Pitlor holds a B.S. from MIT and serves as personal advisor to several CEOs.

R. Patrick Maxwell became a director of our company in 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 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.

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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.

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. From January 1996 to September 1998, he was employed by the Bard Medical Division in the positions of Territory Manager and Sales Training. From May 1987 to January 1996, Mr. Heinemann was employed by the Bard Urological Division in various positions of Sales Consulting and Training Management. Prior to that time, Mr. Heinemann was employed by surgical device divisions of Squibb and Sterling Drug in various sales management positions. Mr. Heinemann holds a B.S. in marketing and personnel management from the School of Business of Eastern Illinois University. He is a member of the Society of Urological Nursing Association, and served on the Board as an Industry Liaison for the Upper Midwest Chapter.

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 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.

Mr. Holman and Ms. Hartjes Holman became husband and wife in 1999.

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.

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Corporate Governance

Compensation Committee

The members of our Compensation Committee are Messrs. Pitlor, Maxwell and Jamison. 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. 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 both members of the Audit Committee are independent directors under SEC rules and has determined that Mr. Maxwell qualifies as an audit committee financial expert under the rules of the SEC.

Board Nominations

We have no standing nominating committee or specific policies or procedures for nomination of board candidates. If the board determines to seek additional candidates in the future, it may create a nominating committee. The board expects that it, or any nominating committee, would identify and qualify new candidates for directors based primarily on the following criteria:

judgment, character, expertise, skills and knowledge useful to the oversight of our business;

diversity of viewpoints, backgrounds, experiences and other demographics;

business or other relevant experience; and

the extent to which the interplay of the candidate s expertise, skills, knowledge and experience with that of other directors will build a board of directors that is effective, collegial and responsive to our needs.

If the board considers additional director candidates in the future, the board intends to consider the entirety of each candidate s credentials and does not have any specific minimum qualifications that must be met in order for a candidate to be recommended as a nominee. However, the board does believe that all its members should have (i) the highest character and integrity, (ii) sound business judgment and an inquiring mind as well as expertise that adds to the composition of the board of directors, (iii) professional experience, education and interest in, and capacity for understanding the complexities of, our operations, (iv) a reputation for working constructively with others, (v) sufficient time to devote to board of directors matters and (vi) no conflict of interest that would interfere with performance as a director.

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.

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Executive Compensation

The following table sets forth, in summary form, the compensation earned in fiscal years 2005, 2004 and 2003 by our current and former Chief Executive Officer and each of the other four most highly compensated executive officers (whom we refer to collectively as the named executive officers).

Summary Compensation Table

		Annual Compensation		Long Term Compensation Awards Securities Underlying
Name and Principal Position	**Fiscal Year**	**Salary ($)**	**Bonus ($)**	**Options (#)**
Sam B. Humphries[1] *President and CEO*	2005	50,558	29,875	400,000
Daniel G. Holman[2]	2005	224,019		100,000
Chairman and CFO	2004	212,192		
	2003	201,183		50,000
Susan Hartjes Holman	2005	153,692		75,000
COO	2004	145,754		
	2003	136,754		40,000
Arie J. Koole	2005	137,219		50,000
Controller	2004	120,546		
Managing Director Dutch subsidiaries	2003	87,441		40,000
Christopher Harris[3]	2005	131,921		50,000
Former VP Research & Development	2004	108,374		
Managing Director UK subsidiary	2003	87,370		40,000
Larry Heinemann	2005	106,346	17,960	75,000
VP Sales & Marketing	2004	91,692	15,500	
	2003	88,050	1,400	40,000

(1) Effective January 1, 2005, Mr. Humphries was appointed our President and Chief Executive Officer.

(2) Mr. Holman resigned as our President and Chief Executive

Officer effective January 1, 2005. Mr. Holman continues to serve as a director and as Chief Financial Officer.

(3) The services of Mr. Harris were terminated after the end of fiscal 2005.

Option Grants in Fiscal 2005

The following table sets forth information concerning option grants granted to each of the named executive officers during fiscal year 2005. The outstanding options listed below may be exercised only upon the vesting of the options. Mr. Humphries options vest in one-quarter installments over a three-year period beginning in January 2005. Mr. Holman s options vested 50% in January 2005 and will vest 25% in each of January 2006 and 2007. The options granted to each of the other named executive officers vest 50% on each of December 21, 2005 and 2006.

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Option Grants in Fiscal 2005

	Individual Grants			
Name	Number of Securities Underlying Options Granted	Percentage of Total Options Granted to Employees in Fiscal 2005	Exercise Price ($/Unit)	Expiration Date
Sam B. Humphries	400,000	44.57%	$ 5.19	01/01/2015
Daniel G. Holman	100,000	11.14%	$ 5.19	01/01/2015
Susan Hartjes Holman	75,000	8.36%	$ 5.30	12/21/2009
Arie J. Koole	50,000	5.57%	$ 5.30	12/21/2009
Christopher Harris	50,000	5.57%	$ 5.30	12/21/2009
Larry Heinemann	75,000	8.36%	$ 5.30	12/21/2009

Option Exercises in Fiscal 2005 and Fiscal Year-End Option Values

None of our named executive officers exercised stock options during fiscal 2005. 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, 2005. The table assumes a per share price of $3.95, which was the closing bid price on March 31, 2005.

			Number of Securities Underlying Unexercised Options at Fiscal Year End (#)		Value of Unexercised In-the-Money Options at Fiscal Year End ($)	
Name	Shares Acquired on Exercise	Value Realized ($)	Exercisable	Unexercisable	Exercisable	Unexercisable
Sam B. Humphries			168,000	312,000	$ 88,100	$ 20,400
Daniel G. Holman			110,000	70,000	$ 132,000	$ 57,000
Susan Hartjes Holman			71,500	53,500	$ 83,900	$ 45,600
Arie J. Koole			55,666	41,000	$ 78,732	$ 45,600
Christopher Harris			55,666	41,000	$ 78,732	$ 45,600
Larry Heinemann			68,166	53,500	$ 78,732	$ 45,600

Employment Agreements

Effective January 1, 2005, Sam B. Humphries became our President and Chief Executive Officer under a written employment agreement with us. This agreement provides Mr. Humphries with an annual base salary of $239,000, subject to annual review. Mr. Humphries is entitled to receive quarterly cash bonuses, ranging from 30% to 60% of his base salary, based on achieving quarterly net sales goals set by our board. In addition, Mr. Humphries is entitled to receive quarterly cash bonuses, ranging from 20% to 40% of his base salary, based on achieving quarterly operating income (loss) goals set by our board. We also granted him options to acquire 400,000 shares of our common stock at an exercise price of $5.19 per share. The options will vest contingent upon Mr. Humphries continued employment in one-quarter installments over a three-year period, beginning on the effective date of his agreement. The options will

fully vest upon a change in control of our company.

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The employment agreement with Mr. Humphries has a one-year term, unless terminated earlier, and will continue to automatically renew on a year-to-year basis. The agreement provides that upon termination of the agreement by us for good cause (as defined in the agreement), we will pay him only the base salary accrued but unpaid through the date of termination. However, if we terminate Mr. Humphries employment because we fail to achieve 100% of the budgeted targets for both net sales and operating income(loss) for five consecutive fiscal quarters, we must pay him an amount equal to 50% of his base salary in effect at the time of termination. If the agreement is terminated (i) without good cause by us, (ii) at the end of the term without renewal, (iii) voluntarily by Mr. Humphries as a result of us imposing material and adverse changes to his principal duties without his consent or (iv) voluntarily by Mr. Humphries after we move our principal executive office more than 100 miles from its current location without his consent, then Mr. Humphries will be entitled to receive an amount equal to 160% of his base salary in effect at the time of termination as well as any base salary accrued but unpaid through the date of termination. The agreement also contains non-competition and non-solicitation provisions, which apply during the term of the agreement and for one year thereafter.

Effective January 1, 2005, we entered into an employment and consulting agreement with Daniel G. Holman. Mr. Holman will serve as Chairman of our Board during the first year of the agreement and as a part-time consultant with the continuing title of Chairman during the second year of the agreement. He also serves as our Chief Financial Officer. Mr. Holman s agreement provides Mr. Holman with a base salary of $239,000 per year during the first year of the agreement, and a consulting fee of $100,000 per year during the second year of the agreement. We also granted him options to purchase 100,000 shares of our common stock at an exercise price equal to $5.19 per share. The options vested 50% on the effective date of his agreement and will vest 25% on each of the first and second anniversaries of the agreement. The options will fully vest upon a change in control of our company.

The employment and consulting agreement with Mr. Holman provides that upon termination of the agreement by us for good cause (as defined in the agreement), we will pay him only his base salary or consulting fees accrued but unpaid through the date of termination. If the agreement is terminated (i) without good cause by us, (ii) voluntarily by Mr. Holman as a result of us imposing material and adverse changes to his principal duties without his consent or (iii) voluntarily by Mr. Holman after we move our principal executive office more than 100 miles from its current location without his consent, then we must pay Mr. Holman any base salary or consulting fees accrued but unpaid through the date of termination, plus an amount equal to the sum of his annual base salary and consulting fees payable during the balance of the term of this agreement as if the agreement had not been terminated. This agreement also contains non-competition and non-solicitation provisions, which apply during the term of the agreement and one year thereafter.

We also have employment agreements with each of Susan Hartjes Holman and Larry Heinemann. The employment agreement of each executive specifies a base salary subject to annual adjustment by mutual agreement of the employee and us, and a severance payment to the employee upon employment termination without cause as defined. Any severance amounts payable under the agreement are limited to the employee s base salary for not less than four months and not longer than twelve months after employment termination, depending on the employee s years of service. Contemporaneously with the execution of their employment agreements, each of these executives executed an Employee Confidentiality, Inventions, Non-Solicitation and Non-Compete Agreement, under which the executive agreed not to disclose confidential information, to assign to us without charge all intellectual property relating to our business which is created or conceived during the term of employment, to not encourage employees to leave our employment for any reason and to not compete with us during the term of employment and for a period of eighteen months thereafter. Also, in connection with the execution of these agreements, we granted these executives varying amounts of stock options to purchase our common stock at the fair market value at date of grant of $7.50 per share. All of these options have lapsed without exercise.

Stock Option Plans

2002 Stock Option Plan

Our 2002 Stock Option Plan provides for the grant of incentive stock options (options that qualify for special tax treatment under Section 422 of the Internal Revenue Code) and non-qualified stock options. Incentive stock options may be granted only to our employees, including employees of any of our subsidiaries. Non-qualified stock options

may be granted to our employees, directors, non-employees or consultants. A total of 650,000 shares of our common stock are available under the plan. As of the date hereof, 35,200 shares remain available for grant. The plan will terminate July 31, 2007, unless terminated earlier by our board.

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Options granted pursuant to the 2002 Stock Option Plan are exercisable, if vested, during a term ending not more than five years from the date of grant. The board may determine at the time of grant whether the entire amount of the options can be exercised at one time or in successive stages. However, upon our change of control, all options vest. The price of the shares subject to the options can be not less than 100% of the fair market value of our common stock on the date of grant. For an employee who already owns more than 10% of our common stock, the exercise price must be at least 110% of the fair market value on the date of grant. We receive no consideration from the key employees to whom we grant options except insofar as certain provisions of the options relating to non-transfer and exercise encourage employees to remain in our employ.

1997 Stock Option Plan

Our 1997 Stock Option Plan terminated in 2003, except as to the 65,859 of options granted under the plan before it lapsed. The Plan provided for the grant of incentive stock options (options that qualify for special tax treatment under Section 422 of the Internal Revenue Code) and non-qualified stock options. Incentive stock options may be granted only to our employees, including employees of any of our subsidiaries. Non-qualified stock options may be granted to our employees, directors, non-employees or consultants.

1995 Stock Option Plan

Our 1995 Stock Option Plan provides for the grant only of non-qualified stock options. These stock options may be granted to our employees, directors, non-employees and consultants. A total of 449,998 shares of common stock have been reserved under the plan. As of the date hereof, 105,431 shares remain available for grant.

Federal Income Tax Consequences of the Operation of the Stock Option Plans

Options granted under the 2002 Plan are intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code. If an optionee purchases shares upon exercise of an incentive option and does not dispose of them before the end of the required holding period, the optionee will recognize gain or loss only upon the ultimate disposition of the shares (except to the extent that the optionee is subject in the year of option exercise to the alternative minimum tax provided for by Sections 56 through 58 of the Internal Revenue Code). Assuming the shares constitute capital assets in the optionee s hands, this recognized gain or loss will be treated as long-term capital gain or loss. In this situation, we will not be entitled to a deduction in connection with the issuance or exercise of the options.

Director Compensation

Non-employee board members receive $500 per board meeting and $500 per Audit Committee meeting attended. In addition, directors participate in our stock option plan. As of August 26, 2005, Messrs. Pitlor, Maxwell and Jamison each hold options to purchase 100,000 shares of common stock. The exercise price of the options range from $1.10 to $5.30 per share. We pay no additional remuneration to Messrs. Humphries or Holman for serving as directors.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In January 2002, we entered into a consulting agreement with Joel R. Pitlor, one of our directors, for management consulting services. Compensation under the agreement was $2,000 per month. The agreement was terminated as of June 30, 2005.

In April 2003, we entered into a consulting agreement with Executive Advisory Group (EAG) for general management advice and guidance as well as strategic and tactical planning services. Sam B. Humphries, our President and Chief Executive Officer, is President of EAG. We initially paid EAG $4,000 per month for Mr. Humphries services, but increased the monthly fee to $6,000 in connection with the increased use of Mr. Humphries time. We have also granted EAG a five-year option to purchase up to 50,000 shares of our common stock, exercisable at $2.80 per share. The agreement was terminated on January 1, 2005.

On April 18, 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix. Sam B. Humphries, our President and Chief Executive Officer, is a former director and consultant of CystoMedix. In connection with his former service to CystoMedix (which terminated prior to negotiations of this agreement), he received 200,000 options to purchase CystoMedix common stock.

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PRINCIPAL AND SELLING SHAREHOLDERS

The following table sets forth the number and percentage of shares of our common stock beneficially owned as of September 13, 2005, for each person known to us to be the beneficial owner of more than five percent of our common stock, each of our directors and named executive officers, all directors and executive officers as a group and the selling shareholder, in each case before and after the consummation of the offering by the selling shareholder. Unless otherwise indicated, the address for each of the shareholders is 2718 Summer Street N.E., Minneapolis, Minnesota 55413.

The number of shares in the Shares Offered column represents all of the shares that the selling shareholder may offer under this prospectus. We do not know when or in what amounts the selling shareholder may offer shares for sale. The selling shareholder may choose not to sell any shares offered by this prospectus. As a result, we cannot estimate the number of shares the selling shareholder will hold after the completion of the offering.

Beneficial ownership and the percentages shown in the following table are calculated in accordance with the rules of the SEC. The percentages are based on 6,873,739 shares outstanding on September 13, 2005. Unless otherwise indicated in the footnotes to the table, to our knowledge, each shareholder identified in the table possesses sole voting and investment power over its shares of common stock, except for those jointly owned with that person s spouse.

	Shares Owned Prior to Offering		Shares Offered	Shares Owned After Offering	
Name of Beneficial Owner	**Number**	**Percentage**	**Number**	**Number**	**Percentage**
5% Shareholders, officers and directors					
Bruce Mindich, M.D. (1)	1,025,259	14.5%			
SF Capital Partners Ltd. (2)	1,000,000	14.5%			
Bonanza Master Fund, Ltd. (3)	571,428	8.3%			
Heartland Advisors, Inc. (4)	550,000	7.9%			
Daniel G. Holman (5)	593,347	8.3%			
Susan Hartjes Holman (6)	593,347	8.3%			
Sam B. Humphries (7)	168,000	2.4%			
R. Patrick Maxwell (8)	122,634	1.8%			
Joel R. Pitlor (9)	117,667	1.7%			
Larry Heinemann (10)	82,166	1.2%			
Thomas E. Jamison (11)	69,100	1.0%			
Arie J. Koole (12)	65,332	*			
All directors and executive officers as group (13)	1,270,913	16.5%			
Selling shareholder					

CCRI Corporation [14]	110,000	100,000

* Represents beneficial ownership of less than one percent of our common stock.

(1) Dr. Mindich s address is c/o Hearts Plus Management Corporation, 200 Route 17 North, Paramus, New Jersey 07652. Of the shares listed, 541,665 shares are beneficially owned by the Mindich Family Limited Liability Company, the General

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Member of which is Dr. Mindich. Includes 183,332 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

(2) The address of SF Capital Partners Ltd. is c/o Stark Offshore Management, LLC, 3600 South Lake Drive, St. Francis, Wisconsin 53235. Excludes 500,000 shares issuable upon the exercise of warrants, which shares are not covered by this prospectus. The warrants are exercisable immediately and expire in April 2010, subject to exercise caps that preclude the holder thereof from utilizing its exercise rights to the extent that it would beneficially own in excess of 4.9% and 9.9% of our outstanding common stock,

giving effect to such exercise. The holder may waive the 4.9% ownership cap, but such waiver will not be effective until the 61st day after delivery thereof. As a result, the holder is not deemed to be the beneficial owner of the shares underlying the warrants as of the date hereof. Michael A. Roth and Brian J. Stark are the managing members of Stark Offshore Management, LLC, which acts as investment manager and has sole power to direct the management of SF Capital Partners. Through Stark Offshore Management, Messrs. Roth and Stark possess voting and dispositive power over the shares held by SF Capital Partners and therefore may be deemed to be beneficial owners of the shares. Messrs. Roth and Stark disclaim

such beneficial ownership based on Schedule 13G filed May 3, 2005.

(3) The address of Bonanza Master Fund, Ltd. is 300 Crescent Court, Suite 1740, Dallas, Texas 75201. Excludes 285,714 shares issuable upon the exercise of warrants, which shares are not covered by this prospectus. The warrants are exercisable immediately and expire in April 2010, subject to exercise caps that preclude the holder thereof from utilizing its exercise rights to the extent that it would beneficially own in excess of 4.9% and 9.9% of our outstanding common stock, giving effect to such exercise. The holder may waive the 4.9% ownership cap, but such waiver will not be effective until the 61st day after delivery thereof. As a result, the reporting persons

are not deemed to be beneficial owners of the underlying common stock with respect to the warrants as of the date hereof. Bonanza Master Fund, Ltd. and Bonanza Capital, Ltd. have shared voting and investment power over the shares. Based on Schedule 13G filed May 2, 2005.

(4) The address of Heartland Advisors is 789 North Water Street, Milwaukee, Wisconsin 53202. Heartland Advisors and William J. Nasgovitz, President and a principal shareholder of Heartland Advisors, may be deemed to have shared voting and investment power over the shares. Each disclaims beneficial ownership over the shares. Based on Schedule 13G/A filed April 8, 2005. Includes

50,000 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

(5) Includes 120,000 shares that Mr. Holman may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005. Includes 121,698 shares beneficially owned by Mr. Holman s spouse, Susan Hartjes Holman, as to which shares Mr. Holman disclaims beneficial ownership. Includes 66,665 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

(6) Includes 79,500 shares that Ms. Holman may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005. Includes 471,649 shares

beneficially owned by Ms. Holman s spouse, Daniel G. Holman, as to which shares Ms. Holman disclaims beneficial ownership. Includes 1,783 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

(7) Includes 168,000 shares that Mr. Humphries may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005. Of the shares listed, 50,000 shares are beneficially owned by the Executive Advisory Group, the President of which is Mr. Humphries.

(8) Mr. Maxwell s address is 2444 Byrnes Road, Minnetonka, Minnesota 55305. Includes 69,000 shares that Mr. Maxwell may acquire upon exercise of options that are

exercisable within 60 days of September 13, 2005. Includes 10,050 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

(9) Mr. Pitlor s address is 237 Moody Street, Waltham, Massachusetts 02453. Includes 69,000 shares that Mr. Pitlor may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005.

(10) Includes 76,166 shares that Mr. Heinemann may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005. Includes 1,250 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

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(11) Mr. Jamison s address is 3902 IDS Center, 80 South Eighth Street, Minneapolis, Minnesota 55402. Includes 69,000 shares that Mr. Jamison may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005.

(12) Mr. Koole s address is Hofkamp 2, 6161 DC Geleen, The Netherlands. Includes 63,666 shares that Mr. Koole may acquire upon exercise of options that are exercisable within 60 days of September 13, 2005.

(13) Includes 761,999 shares that our directors and executive officers may acquire upon exercise of options that are exercisable within 60 days

of September 13, 2005. Includes 79,748 shares issuable upon exercise of warrants that are exercisable beginning on the date of this prospectus.

(14) The address of CCRI Corporation is 70 Frenchtown Road, Suite 300, North Kingstown, Rhode Island 02852. Includes 100,000 shares issuable upon exercise of warrants.

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DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 20,000,000 shares of common stock, $0.01 par value per share. As of September 13, 2005, we had outstanding 6,873,739 shares of common stock and 527 holders of records with respect to our common stock.

The following summary of provisions of our capital stock describes the material provisions of our articles of incorporation and our by-laws, which are included as exhibits to the registration statement of which this prospectus forms a part.

Common Stock

Each outstanding share of common stock is entitled to one vote on all matters submitted to a vote of shareholders. There is no cumulative voting. Holders of our common stock are entitled to share equally, share for share, if dividends are declared on our common stock. Upon liquidation dissolution or winding up of our company, the holders of common stock are entitled to share equally, share for share, in our assets which are legally available for distribution, after payment of amounts payable to creditors. The shares of our common stock are not convertible and holders thereof have no preemptive rights. All issued and outstanding shares of common stock are fully paid and nonassessable.

Warrants

In connection with the private placement of our common stock on April 21, 2005, we issued warrants to purchase 1,180,928 shares of common stock. The warrants are exercisable for five years at an exercise price of $4.75 per share. Subject to various exceptions, we have agreed to reduce the exercise price of the warrants in the event that, within one year from the closing of the private placement, we issue common stock at less than $3.50 per share. We generally may call for the investors to exercise their warrants beginning two years after the closing if, for 30 consecutive trading days prior to making this call, the closing price for our stock is at least $9.00 per share and the average trading volume is 5,000 shares.

As part of a consulting agreement with CCRI Corporation, we issued a warrant to purchase 50,000 shares of common stock at a price of $3.00 per share on April 1, 2003, and an additional warrant to purchase 50,000 shares at a price of $5.00 on November 2, 2003. The warrants expire five years from the date of issue. This prospectus covers the resale of the shares underlying these warrants.

In connection with our subscription rights offering in July 2002, we issued 798,213 warrants to purchase our common stock, exercisable for two years at $2.00 per share. However, we suspended the exercise of these 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 unexercised warrants lapsed 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 this registration statement covering the shares underlying the new warrants. This prospectus is included as part of that new registration statement.

Indemnification of Directors and Officers and Limitation on Liability

Our restated articles of incorporation provide that our directors will not be liable to us or our shareholders for monetary damages for any breach of fiduciary duty, except to the extent otherwise not permitted under Section 302A.251 of the Minnesota Business Corporation Act. This provision will not prevent our shareholders from obtaining injunctive or other relief against our directors nor does it shield our directors from liability under federal or state securities laws.

Our bylaws require us to indemnify our directors and officers to the extent permitted by Section 302A.521 of the Minnesota Business Corporation Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons in accordance with the provisions contained in our articles and by-laws, or otherwise, we have been advised that, in the opinion of the Securities and Exchange Commission, this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

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Transfer Agent and Registrar

The transfer agent and registrar for our common stock is StockTrans, Inc.

PLAN OF DISTRIBUTION

Common Stock Offered by Us

We intend to distribute copies of this prospectus to record holders of our warrants promptly following the effective date of the registration statement of which this prospectus forms a part. If you desire to purchase shares of common stock underlying your warrants, you must properly exercise the warrants on or before 5:00 p.m., Minneapolis time, on _____ ___, 2005. If you do not exercise your warrants before the expiration date, your unexercised warrants will expire and have no value.

To exercise your warrant, you must complete and sign the warrant exercise form attached to your warrant certificate and deliver it, along with your certificate and full payment of the total exercise price of the shares being purchased, to our principal office. You may pay the exercise price by cash or check payable to the order of our company. Our principal office is located at:

Uroplasty, Inc.
2718 Summer Street N.E.
Minneapolis, MN 55413-2820

Our employees, officers and directors may solicit exercises of warrants by warrant holders. These persons will not receive any commissions or compensation for their services.

Our board of directors is not making any recommendation to you as to whether you should exercise your warrants. You must make your own decision regarding whether to exercise your warrants.

Common Stock Offered by Selling Shareholder

The selling shareholder and any of its pledgees, donees, transferees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling shareholder may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits investors;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

to cover short sales made after the date that this Registration Statement is declared effective by the SEC;

broker-dealers may agree with the selling shareholders to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale; and

any other method permitted pursuant to applicable law.

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The selling shareholder may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling shareholder may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholder (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling shareholder does not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling shareholder may from time to time pledge or grant a security interest in some or all of the shares owned by it and, if the selling shareholder defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus.

Upon our company being notified in writing by a selling shareholder that any material arrangement has been entered into with a broker-dealer for the sale of common stock through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing (i) the name of each such selling shareholders and of the participating broker-dealer(s), (ii) the number of shares involved, (iii) the price at which such shares of common stock were sold, (iv) the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable, (v) that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and (vi) other facts material to the transaction. In addition, upon our company being notified in writing by a selling shareholder that a donee or pledgee intends to sell more than 500 shares of common stock, a supplement to this prospectus will be filed if then required in accordance with applicable securities law.

The selling shareholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling shareholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with those sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, that can be attributed to the sale of the shares will be paid by the selling shareholders and/or the purchasers. The selling shareholder has represented and warranted to us that it acquired the securities subject to this registration statement in the ordinary course of such selling shareholder s business and, at the time of its purchase of such securities such selling shareholder had no agreements or understandings, directly or indirectly, with any person to distribute any such securities.

We have advised the selling shareholder that it may not use shares registered on this Registration Statement to cover short sales of common stock made prior to the date on which this Registration Statement shall have been declared effective by the SEC. If a selling shareholder uses this prospectus for any sale of the common stock, it will be subject to the prospectus delivery requirements of the Securities Act. The selling shareholder will be responsible to comply with the applicable provisions of the Securities Act and Exchange Act, and the rules and regulations thereunder promulgated, including, without limitation, Regulation M, as applicable to such selling shareholder in connection with resales of its shares under this Registration Statement.

We are required to pay all fees and expenses incident to the registration of the shares, but we will not receive any proceeds from the sale of the common stock. If the selling shareholder uses this prospectus for any sale of the common stock, it will be subject to the prospectus delivery requirements of the Securities Act.

VALIDITY OF COMMON STOCK

The validity of the shares of common stock offered by this prospectus will be passed upon by Messerli & Kramer P. A.

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EXPERTS

The consolidated financial statements of Uroplasty, Inc. as of March 31, 2005 and for the year then ended included in this prospectus have been so included in reliance upon the report of McGladrey & Pullen, LLP, independent registered public accounting firm, given on the authority of said firm as experts in accounting and auditing.

The consolidated financial statements of Uroplasty, Inc. as of March 31, 2004 and for the year then ended have been included herein in reliance upon the report of KPMG LLP, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a Registration Statement on Form SB-2 under the Securities Act with the SEC with respect to this offering. This prospectus, which is included in the registration statement, does not contain all of the information included in the registration statement. Parts of the registration statement are omitted in accordance with the rules and regulations of the SEC. For further information about us and our common stock, we refer you to the registration statement.

We are subject to the informational requirements of the Exchange Act and file reports, proxy statements, and other information with the SEC. Such reports, proxy statements, and other information, as well as the registration statement and the exhibits and schedules thereto, may be inspected, without charge, at the public reference facility maintained by the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of such material may also be obtained from the Public Reference Section of the SEC at 450 Fifth Street, N.W., Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the SEC s Public Reference Room in Washington, D.C. by calling the SEC at 1-800-SEC-0330. Such materials can also be inspected on the SEC s website at *www.sec.gov*.

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Uroplasty, Inc. and Subsidiaries

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Uroplasty, Inc.
Minneapolis, Minnesota

We have audited the consolidated balance sheet of Uroplasty, Inc. and Subsidiaries as of March 31, 2005, and the related consolidated statements of operations, shareholders equity and comprehensive loss, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Uroplasty, Inc. and subsidiaries as of March 31, 2005, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ McGladrey & Pullen, LLP
Minneapolis, Minnesota
June 22, 2005

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Shareholders
Uroplasty, Inc.

We have audited the accompanying consolidated balance sheet of Uroplasty, Inc. and Subsidiaries as of March 31, 2004, and the related consolidated statements of operations, shareholders equity and comprehensive loss, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Uroplasty, Inc. and subsidiaries as of March 31, 2004, and the results of their operations and their cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Minneapolis, Minnesota
July 26, 2004

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
March 31, 2005 and 2004

	2005	2004
Assets		
Current assets:		
Cash and cash equivalents	$ 1,492,684	$ 2,697,670
Accounts receivable, net	944,527	1,065,176
Income tax receivable	114,189	
Inventories	547,476	519,130
Other	161,920	235,078
Total current assets	3,260,796	4,517,054
Property, plant, and equipment, net	1,040,253	1,071,116
Intangible assets, net of accumulated amortization of $225,090 and $222,014, respectively	39,100	51,495
Deferred tax assets	103,075	123,893
Total assets	$ 4,443,224	$ 5,763,558

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
March 31, 2005 and 2004

	2005	2004
Liabilities and Shareholders Equity		
Current liabilities:		
Current maturities long-term debt	$ 44,606	$ 42,301
Accounts payable	362,994	225,315
Accrued liabilities:		
Compensation and payroll taxes	284,255	197,939
Income taxes		101,562
Foreign sales tax	181	13,130
Royalties	24,710	29,006
Clinical	12,702	52,767
Audit and tax-consulting	45,566	32,056
Legal	22,750	61,663
Other	88,518	89,396
Total current liabilities	886,282	845,135
Long-term debt less current maturities:	461,265	479,720
Accrued pension liability	303,781	334,470
Total liabilities	1,651,328	1,659,325
Commitments and Contingencies		
Shareholders equity:		
Common stock $.01 par value; 20,000,000 shares authorized, 4,699,597 and 4,584,802 shares issued and outstanding at March 31, 2005 and 2004, respectively	46,996	45,848
Additional paid-in capital	9,366,644	9,130,580
Accumulated deficit	(6,491,387)	(4,756,622)
Accumulated other comprehensive loss	(130,357)	(315,573)
Total shareholders equity	2,791,896	4,104,233
Total liabilities and shareholders equity	$ 4,443,224	$ 5,763,558

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Years ended March 31, 2005 and 2004

	2005	2004
Net sales	$ 6,657,726	$ 5,714,896
Cost of goods sold	1,755,456	1,452,331
Gross profit	4,902,270	4,262,565
Operating expenses		
General and administrative	2,260,240	2,069,568
Research and development	2,258,127	1,820,690
Selling and marketing	2,015,655	1,714,475
	6,534,022	5,604,733
Operating loss	(1,631,752)	(1,342,168)
Other income (expense)		
Interest income	30,168	30,173
Interest expense	(25,934)	(21,995)
Foreign currency exchange gain (loss)	(15,744)	45,882
Other		6,000
	(11,510)	60,060
Loss before income taxes	(1,643,262)	(1,282,108)
Income tax expense	91,503	229,185
Net loss	$ (1,734,765)	$ (1,511,293)
Net loss per common share:		
Basic and diluted	$ (0.37)	$ (0.33)
Weighted average common shares outstanding:		
Basic and diluted	4,651,732	4,517,979

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY AND COMPREHENSIVE LOSS
Years ended March 31, 2005 and 2004

	Common Stock		Additional Paid-in	Accumulated		Accumulated Other Comprehensive	Total Shareholders
	Shares	Amount	Capital	Deficit	Vendor Deposit	Loss	Equity
Balance at March 31, 2003	4,488,971	$ 44,890	$ 8,457,901	$ (3,245,329)	$ (112,000)	$ (503,835)	$ 4,641,627
Exercise of stock options	23,931	239	37,405				37,644
Warrants conversion	23,600	236	46,964				47,200
Employee retirement savings plan contribution	13,300	133	57,647				57,780
Non-employee stock-based consulting and compensation expense	35,000	350	472,663				473,013
Release of restricted common stock to vendor			58,000		112,000		170,000
Net loss				(1,511,293)			(1,511,293)
Translation adjustment						239,323	239,323
Additional pension liability						(51,061)	(51,061)
Total comprehensive loss							(1,323,031)
Balance at March 31, 2004	4,584,802	45,848	9,130,580	(4,756,622)		(315,573)	4,104,233

Exercise of stock options	38,300	383	67,638				68,021
Warrants conversion	68,395	684	136,107				136,791
Employee retirement savings plan contribution	8,100	81	32,319				32,400
Net loss				(1,734,765)			(1,734,765)
Translation adjustment						150,505	150,505
Additional pension liability						34,711	34,711
Total comprehensive loss							(1,549,549)
Balance at March 31, 2005	4,699,597	$ 46,996	$ 9,366,644	$ (6,491,387)	$	$ (130,357)	$ 2,791,896

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years ended March 31, 2005 and 2004

	2005	2004
Cash flows from operating activities:		
Net loss	$ (1,734,765)	$ (1,511,293)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation	144,911	140,884
Amortization	18,968	23,300
Loss on disposal of assets	3,751	
Stock-based consulting expense		473,013
Deferred tax assets	23,680	(29,734)
Changes in operating assets and liabilities:		
Accounts receivable	168,779	31,902
Inventories	21,896	40,217
Other current assets	78,867	(23,689)
Accounts payable	162,526	67,125
Accrued liabilities	(221,646)	163,893
Accrued pension liability	(38,909)	93,262
Additional pension liability	36,537	(51,061)
Net cash used in operating activities	(1,335,405)	(582,181)
Cash flows from investing activities:		
Payments for property, plant and equipment	(74,966)	(115,352)
Payments relating to intangible assets	(7,277)	(26,581)
Net cash used in investing activities	(82,243)	(141,933)
Cash flows from financing activities:		
Repayment of long-term debt	(43,356)	(40,419)
Net proceeds from issuance of common stock	204,812	84,844
Net cash provided by financing activities	161,456	44,425
Effect of exchange rates on cash and cash equivalents	51,206	1,378
Net decrease in cash and cash equivalents	(1,204,986)	(678,311)
Cash and cash equivalents at beginning of year	2,697,670	3,375,981

Cash and cash equivalents at end of year	$ 1,492,684	$ 2,697,670
Supplemental disclosure of cash flow information:		
Cash paid during the year for interest	$ 24,751	$ 23,517
Cash paid during the year for income taxes	304,018	130,282
Supplemental disclosure of non-cash financing and investing activities:		
Shares issued for 401(k) plan profit sharing contribution	32,400	57,780
Vesting of restricted shares for mold purchase		170,000
Minimum pension liability, net of tax	(34,711)	51,061

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2005 and 2004

1. Summary of Significant Accounting Policies

Nature of Business. We are a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions. We have developed, and are developing, minimally invasive products primarily for the treatment of urinary and fecal incontinence and overactive bladder symptoms. We currently sell our products outside of the United States and are pursuing regulatory approvals to market our products in the United States. We are increasing our sales and marketing activities in the U.S. as we obtain such approvals. The FDA approval process can be costly, lengthy and uncertain.

Principles of Consolidation. Our consolidated financial statements include the accounts of the Company and our wholly owned foreign subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Revenue Recognition. We recognize revenue upon shipment of product to customers. Upon shipment, the risks and rewards of ownership are passed on to the buyer. There are no customer acceptance provisions. We sell our products to distributors who sell to other distributors and end users, and to end users in the United Kingdom. Sales to distributors were $4,700,000 and $3,800,000 in fiscal 2005 and 2004, respectively, or 70% and 66%, respectively, of net sales. Payment terms range from prepayment to 60 days. The distributor payment terms are not contingent on the distributor selling the product to other distributors or end users. Customers do not have the right to return unsold product to us except for warranty claims. We offer customary product warranties. During fiscal 2005, two customers accounted for approximately 15% and 11% of our net sales. During fiscal 2004, the same two customers accounted for approximately 13% and 11% of our net sales.

Cash and Cash Equivalents. We consider highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. We maintain our cash in bank accounts, which, at times, exceed federally insured limits. We have not experienced any losses in such accounts.

Accounts Receivable. Accounts receivable are carried at the original invoice amount less an estimate made for doubtful receivables based on a periodic review of all outstanding amounts. We determine the allowance for doubtful accounts based on customer financial condition, and both historical and expected credit loss experience. Accounts receivable are written off when deemed uncollectible. Recoveries of accounts receivable previously written off are recorded when received. The allowance for doubtful accounts was $218,000 and $33,000 at March 31, 2005 and 2004, respectively.

Patents. Patents are stated at cost and are amortized over six years using the straight-line method.

Income Taxes. Deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to be applied to taxable income in the years in which those temporary differences are expected to be recovered or settled. During fiscal 2005 and 2004, our Dutch subsidiaries recorded income tax expense of $91,503 and $229,185 respectively, as they have fully utilized their net operating loss carryforwards. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions.

Use of Estimates. The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates. Our significant accounting policies and estimates include revenue recognition, accounts receivable, valuation of inventory, foreign currency translation/transactions, and the determination of recoverability of long-lived and intangible assets.

Product Warranty. We warrant our new products to be free from defects in material and workmanship under normal use and service for a period of twelve months after date of sale. Under the terms of these warranties, we are obligated to repair or replace the products we deem to be defective due to material or workmanship. We do not have an accrual for warranty costs, as warranty claims are infrequent and immaterial.

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Inventories. Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value) and consist of the following at March 31, 2005 and 2004:

	2005	2004
Raw materials	$ 193,980	$ 138,920
Work-in-process	75,337	110,511
Finished goods	278,159	269,699
	$ 547,476	$ 519,130

Property, Plant, and Equipment. Property, plant, and equipment are carried at cost and consist of the following at March 31, 2005 and 2004:

	2005	2004
Land	$ 158,861	$ 150,652
Building	692,646	656,855
Equipment	1,391,516	1,369,847
	2,243,023	2,177,354
Less accumulated depreciation	(1,202,770)	(1,106,238)
	$ 1,040,253	$ 1,071,116

Depreciation is provided using the straight-line method over useful lives of three to seven years for equipment and 40 years for the building. Maintenance and repairs are charged to expense as incurred. Renewals and betterments are capitalized and depreciated over their estimated useful service lives.

Intangible Assets. Intangible assets are comprised of patents and trademarks which are amortized on a straight-line basis over their estimated useful lives, generally six years.

Estimated annual amortization for these assets for the years ended March 31, are as follows:

2006	$ 15,414
2007	8,512
2008	5,756
2009	5,652
2010	3,369
Thereafter	397
	$ 39,100

Impairment of Long-Lived Assets. Long-lived assets at March 31, 2005 consist of property, plant and equipment. 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. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of

the carrying amount or fair value less costs to sell.

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Research and Development. Research and development costs are expensed as incurred and consist of the following for the years ended March 31, 2005 and 2004:

	2005	2004
FDA regulatory costs	$ 809,281	$ 745,690
Other research and development costs	1,448,846	1,075,000
	$ 2,258,127	$ 1,820,690

Foreign Currency Translation. All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. The resulting translation adjustment is recorded within accumulated other comprehensive loss, a separate component of shareholders equity. Foreign currency transaction gains and losses are recognized currently in the consolidated statement of operations, including unrealized gains and losses on short-term inter-company obligations using period-end exchange rates. Unrealized gains and losses on long-term inter-company obligations are recognized within accumulated other comprehensive loss, a separate component of shareholders equity.

Exchange gains and losses are recognized 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 intercompany obligations between us and our foreign subsidiaries. We recognized net foreign currency gains (losses) of $(15,744) and $45,882 for the years ended March 31, 2005 and 2004, respectively.

Stock-Based Compensation. We apply the intrinsic-value method to account for employee stock-based compensation. As such, compensation expense, if any, is determined on the date of grant if the current market price of the underlying stock exceeds the exercise price.

We account for stock-based instruments granted to non-employees under the fair value method of Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123) and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Under SFAS No. 123, options are recorded at their fair value on the measurement date, which is typically the vesting date.

Stock Option Plans. Had we determined compensation cost based on the fair value at the grant date for our stock options under SFAS No. 123, our net loss would have changed to the pro forma amounts shown below:

	2005	2004
Net loss As reported	$ (1,734,765)	$ (1,511,293)
Add: Total stock-based employee compensation expense determined under intrinsic value based method for all awards		
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(2,321,745)	(253,374)
Net loss Pro forma	$ (4,056,510)	$ (1,764,667)
Net loss per common share As reported:		
Basic and diluted	$ (0.37)	$ (0.33)
Net loss per common share Pro forma:		
Basic and diluted	$ (0.87)	$ (0.39)

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The per share weighted-average fair value of stock options granted during 2005 and 2004 was $4.63 and $1.86, respectively, on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2005	2004
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	3.40%	2.93%
Expected volatility	117%	118%
Expected life, in years	7.40	5.00

Basic and Diluted Net Loss per Common Share. Basic per common share amounts are calculated by dividing net loss by the weighted-average common shares outstanding. Diluted per common share amounts are computed similar to basic per common share amounts except that the weighted-average shares outstanding are increased to include additional shares for the assumed exercise of stock options and warrants, if dilutive. Because we had a loss in fiscal 2005 and 2004, diluted shares were the same as basic shares since the effect of options and warrants would have been anti-dilutive. The following options and warrants outstanding at March 31, 2005 and 2004 to purchase shares of common stock were excluded from diluted loss per share as their impact would be anti-dilutive as follows:

	Number of Options/Warrants		Range of exercise prices
Years ended:			
March 31, 2005	1,820,859	$	0.90-10.50
March 31, 2004	1,718,966	$	0.90-10.50

New Accounting Pronouncements.

In May 2005, the FASB issued FASB Statement No. 154, *Accounting Changes and Error Corrections*. This new standard replaces APB Opinion No. 20, *Accounting Changes*, and FASB Statement No. 3, *Reporting Accounting Changes in Interim Financial Statements.* Among other changes, Statement 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle, unless it is impracticable to do so. Statement 154 also provides that (1) a change in method of depreciating or amortizing a long-lived nonfinancial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle, and (2) correction of errors in previously issued financial statements should be termed a restatement. The new standard is effective for accounting changes and correction of errors made in fiscal years 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 FASB Statement 154 will have a material effect on our financial position or results of operations.

In November 2004, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, 151, *Inventory Costs, An Amendment of Accounting Research Bulletin No. 43, Chapter 4,* which adopts wording from the International Accounting Standards Board s, or IASB, IAS 2 *Inventories* in an effort to improve the comparability of cross-border financial reporting. The new standard 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 fiscal 2007. We do not expect adoption to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued SFAS 123(R), *Share-Based Payment*, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation,* and supersedes APB Opinion 25, *Accounting for Stock Issued to Employees.* SFAS 123(R) 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 and is effective for us beginning on April 1, 2006. We expect the provisions of SFAS 123(R) to result in a significant charge to compensation expense, as we currently do not recognize stock compensation expense in accordance with SFAS

123(R).

In March 2005, FASB Interpretation No.47 FIN 47 was issued, which clarifies certain terminology as used in FASB Statement No. 143, Accounting for Asset Retirement Obligations. In addition it clarifies when an entity would have sufficient information to reasonably estimate the fair value of an asset retirement obligation. FIN 47 is effective no later than the end of fiscal years ending after December 15, 2005. Early adoption of FIN 47 is encouraged. The Company believes the adoption of FIN 47 will have no impact on the financials of the Company, once adopted.

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2. Notes Payable

Notes payable consist of the following at March 31, 2005 and 2004:

	2005	2004
Mortgage note, monthly payments of $3,145 plus variable rate interest through November 2017 (rate at March 31, 2005 4.1%)	$ 482,467	$ 493,327
Note payable, monthly payments of $571 plus fixed rate interest through August 2008 (rate until August 2008 4.4%)	23,404	28,694
	505,871	522,021
Less current maturities	44,606	42,301
	$ 461,265	$ 479,720

Future approximate payments of long-term debt for the years ended March 31, are as follows:

2006	$ 44,606
2007	44,606
2008	44,606
2009	40,595
2010	37,738
Thereafter	293,720
	$ 505,871

In March 2005, we entered into a business loan agreement with Venture Bank, pursuant to which we may borrow up to $500,000 on a revolving basis. All amounts which the bank advances to us are due in March 2006, unless the bank renews the agreement. Amounts advanced to us accrue interest at a variable rate of 1% in excess of the published prime rate in the Wall Street Journal, with a minimum rate of 6% per annum. We are obligated to pay interest monthly on the outstanding principal balance. Advances under this agreement are secured by substantially all of our assets. At March 31, 2005, we had no outstanding balances under the agreement.

3. Shareholders Equity

Stock Options. We have reserved 1,928,811 shares of our common stock for issuance to employees, directors, consultants, and independent contractors. Outstanding options generally expire five years from date of grant and vest at varying rates ranging up to five years. On January 1, 2005, we granted 500,000 options to purchase common stock to certain officers with an expiration period of ten years from date of grant. Options are granted at the discretion of the directors and are exercisable in amounts equal to or greater than the fair market value of our common stock at date of grant. The plans provide for the exercise of options during a limited period following termination of employment, death or disability.

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Stock option activity under these plans is summarized as follows:

	Shares Outstanding	Weighted average exercise price per share
Balance at March 31, 2003	841,911	$ 2.87
Granted	90,000	2.59
Exercised	(23,931)	1.57
Cancelled	(53,627)	4.12
Balance at March 31, 2004	854,353	2.80
Granted	1,047,400	5.24
Exercised	(38,300)	1.78
Cancelled	(142,594)	7.16
Balance at March 31, 2005	1,720,859	$ 3.96

The following table summarizes information concerning currently outstanding and exercisable options by price.

Price	Number of shares outstanding	Weighted average remaining life in years	Number exercisable
$ 0.90	1,200	2.58	400
1.10	396,400	2.42	237,800
2.25	30,000	8.00	12,000
2.40	144,192	1.50	144,192
2.80	50,000	3.00	50,000
3.50	10,000	3.50	10,000
3.75	5,000	4.25	5,000
4.10	500	4.83	250
5.19	500,000	9.75	150,000
5.25	3,333	0.33	3,333
5.30	541,900	4.75	270,950
6.75	35,000	0.30	35,000
10.50	3,334	0.67	3,334
	1,720,859		922,259

Warrants. 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 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 this registration statement covering the shares underlying these warrants. In April 2005, we recognized a liability of $1.4 million associated with the grant of these warrants. The value of these warrants has been determined using the Black-Scholes option-pricing model. We reported expense of approximately $686,000 in the first quarter of fiscal 2006 due to the increase in fair value of these warrants from their date of issue through

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June 30, 2005. This fair value adjustment will be continued for each warrant until such time as the warrant is exercised or expires.

As part of a consulting agreement with CCRI Corporation (CCRI), we issued a warrant to purchase 50,000 shares of common stock at a price of $3.00 per share on April 1, 2003, and an additional warrant to purchase 50,000 shares at a price of $5.00 on November 2, 2003. At March 31, 2005, all of these warrants were outstanding and expire five years from date of issue.

Other Comprehensive Loss. Other comprehensive loss consists of accumulated translation adjustment, and accumulated additional pension liability as follows:

	Accumulated translation adjustment	Accumulated additional pension liability	Total
Balance at March 31, 2003	$ (454,401)	$ (49,434)	$ (503,835)
Translation adjustment	239,323		239,323
Additional pension liability		(51,061)	(51,061)
Balance at March 31, 2004	(215,078)	(100,495)	(315,573)
Translation adjustment	150,505		150,505
Additional pension liability		34,711	34,711
Balance at March 31, 2005	$ (64,573)	$ (65,784)	$ (130,357)

Consulting Agreements. On April 1, 2003, we executed a consulting agreement with CCRI to provide investor relations and development services. We pay CCRI a monthly fee of $4,000 plus expenses. CCRI received 35,000 shares of fully vested restricted common stock, and vested warrants to purchase 50,000 shares of common stock at an exercise price of $3.00 per share, and received vested warrants to purchase 50,000 shares of common stock at an exercise price of $5.00 per share on November 2, 2003. We recorded the fair value of the common stock and the warrants aggregating $212,974, as of April 1, 2003, in shareholders equity as additional paid-in capital and deferred compensation, which was fully amortized as of April 30, 2003. The balance was amortized over the 1-year service period. Also, we recorded the fair value of the additional warrants to acquire 50,000 of common stock aggregating $144,200, as of November 2, 2003, as deferred compensation in shareholders equity. This balance was amortized over the remaining 5 months of the 1-year service period. Stock-based compensation expense for CCRI agreement for the year ended March 31, 2004 aggregated $357,174. On April 1, 2004, we extended the agreement for one year. The monthly fee of $4,000 plus expenses remained the same.

On April 1, 2003, we executed a consulting agreement with Executive Advisory Group (EAG) to provide general management advice and guidance as well as strategic and tactical planning services. Mr. Sam B. Humphries, at that time a director of the Company, was President of EAG. We paid EAG a monthly fee of $6,000 plus expenses and granted to EAG stock options to purchase 50,000 shares of common stock, exercisable at $2.80 per share. We fully amortized the fair value of the stock options in fiscal 2004. Stock-based compensation expense for the EAG agreement for the year ended March 31, 2004 aggregated $115,839. On April 1, 2004, we extended the agreement. The monthly fee of $6,000 plus expenses remained the same. This agreement was terminated on January 1, 2005, the date Mr. Humphries was appointed our President and Chief Executive Officer.

The options and warrants issued to EAG and CCRI to acquire an aggregate of 150,000 shares of common stock were fully vested upon issuance. The fair value of these instruments was determined using the Black-Scholes options pricing model with the following variables:

	April 1, 2003	November 2, 2003
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	2.93%	3.29%
Expected volatility	118%	113%
Expected life, in years	5.00	5.00

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4. Commitments and Contingencies

Royalties. We have received an absolute assignment of a patent relating to the Macroplastique Implantation System from a British surgeon, in return for a royalty for each unit sold during the life of the patent. The aggregate amount of royalty expense that we recognized pursuant to such royalty agreement during the fiscal years ended March 31, 2005 and 2004 was $18,042 and $13,802, respectively.

Under the terms of an agreement with former officers and directors of ours, we pay royalties equal to between three percent and five percent of the net sales of certain products, subject to a specified monthly minimum of $4,500. The royalties payable under this agreement will continue until the patent referenced in the agreement expires in 2010. Total expense recognized under the agreement was $181,598 and $162,047 for the fiscal years ended March 31, 2005 and 2004, respectively.

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

In April 2005, we entered into an exclusive manufacturing and distribution agreement with CystoMedix for the Urgent PC product. We paid CystoMedix an initial royalty payment of $225,000 and are paying an additional $250,000 in 12 monthly installments of $20,833. We will also pay CystoMedix a 7% royalty on product sales. However, the 7% royalty is first offset against the monthly royalty installments.

Option for Asset Acquisition. CystoMedix has granted us an exclusive option to acquire 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. We may exercise the option between January 2006 and 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 our option.

Purchase Requirements. We have agreed to purchase our entire requirement of product components from CL Medical. We also have specified minimum purchase requirements of $240,000 of units in the first year after FDA clearance of I-Stop, increasing to approximately $1.9 million of units over a five-year period, subject to periodic adjustment based on the value of the euro.

Operating Lease Commitments. We lease office, warehouse, and production space under three operating leases and lease various automobiles for our European employees. At March 31, 2005, minimum lease payments under noncancelable operating leases with an initial term in excess of one year for the ensuing years ending March 31 are as follows:

2006	$ 315,195
2007	94,588
2008	28,687
2009	4,635
	$ 443,105

Total rent expense paid for operating leases was $386,614 and $383,624 in fiscal 2005 and 2004, respectively.

Employment Agreements. We entered into employment agreements with certain officers, the terms of which, among other things, specify a base salary subject to annual adjustment by mutual agreement of the parties, and a severance payment to the employee upon employment termination without cause. Any severance amounts payable under the agreement shall be limited to the employee s base salary for not less than four months and not longer than twelve months after employment termination, depending on the employee s years of service. Contemporaneously with the execution of the employment agreement, each of the officers executed an Employee Confidentiality, Inventions, Non-Solicitation, and Non-Compete Agreement, certain terms of which specify the employee shall not disclose

confidential information, shall assign to us without charge all intellectual property relating to our business which is created or conceived during the term of employment, shall not encourage employees to leave our employment for any reason and shall not compete with us during the term of employment and for a period of eighteen months thereafter.

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5. Savings and Retirement Plans

We sponsor various plans for eligible employees in the United States, the United Kingdom (UK), and The Netherlands. Our retirement savings plan in the United States conforms to Section 401(k) of the Internal Revenue Code and participation is available to substantially all employees. We may also make discretionary contributions ratably to all eligible employees. Our contributions in fiscal 2005 and 2004 in the United States were made in the form of our common stock and became fully vested when made. The total contribution expense associated with these plans in the United States was $32,481 and $30,156 for the fiscal years ended March 31, 2005 and 2004, respectively.

Our international subsidiaries have defined benefit retirement plans for eligible employees. These plans provide benefits based on the employee s years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. The Company s UK subsidiary defined benefit plan was frozen on December 31, 2004. On March 10, 2005, the UK subsidiary established a defined contribution plan.

The cost for our plans in The Netherlands and United Kingdom include the following components for the years ended March 31, 2005 and 2004:

	2005	2004
Gross service cost, net of employee contribution	$ 141,745	$ 102,564
Interest cost	89,031	71,165
Expected return on assets	(56,001)	(44,102)
Amortization	56,394	62,606
Net periodic retirement cost	$ 231,169	$ 192,233

The following summarizes the change in benefit obligation and the change in plan assets for the years ended March 31, 2005 and 2004:

	2005	2004
Projected benefit obligation, beginning of year	$ 1,503,534	$ 1,126,749
Service cost	141,745	102,564
Interest cost	89,031	71,165
Other	(11,759)	18,792
Actuarial result	254,618	18,387
Foreign currency translation	84,867	165,877
Projected benefit obligation, end of year	$ 2,062,036	$ 1,503,534
Plan assets, beginning of year	$ 998,620	$ 713,438
Contributions to plan	210,124	198,500
Benefits paid	(9,415)	(5,586)
Actual return on assets	(3,588)	(17,767)
Foreign currency translation	50,661	110,035
Plan assets, end of year	$ 1,246,402	$ 998,620

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The funded status of our pension retirement plans at March 31, 2005 and 2004, are as follows:

	2005	2004
Funded status	$ (815,634)	$ (504,914)
Unrecognized net loss	638,684	296,909
Minimum pension liability	(103,122)	(153,525)
Accrued pension liability	$ (280,072)	$ (361,530)

Major assumptions used in the above calculations include:

	2005	2004
Discount rate	4.50-5.50%	5.25-5.75%
Expected return on assets	4.00-5.00%	4.50-5.00%
Expected rate of increase in future compensation general	3%	3%
individual	0%-3%	0%-3%

6. Income Taxes

The components of income tax expense for the years ended March 31, 2005 and 2004, consist of the following:

	2005	2004
Income tax provision:		
Current:		
U.S. and state	$	$
Foreign	79,585	232,025
Deferred:		
U.S. and state		
Foreign	11,918	(2,840)
Total income tax expense	$ 91,503	$ 229,185

Effective tax rates differ from statutory federal income tax rates for the year ended March 31, 2005 and 2004 as follows:

	2005	2004
Statutory federal income tax benefit	$ (589,820)	$ (435,917)
State tax benefit		(56,658)
Valuation allowance increase	792,685	715,023
UK temporary differences not previously tax effected	(109,983)	
Other	(1,379)	6,737
	$ 91,503	$ 229,185

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Deferred taxes as of March 31, 2005 and 2004 consist of the following:

	2005	2004
Deferred tax assets:		
Pension liability	$ 110,405	$ 133,916
Other reserves and accruals	70,619	35,000
Deferred profit on intercompany sales	186,166	166,000
Net operating loss carryforwards	4,018,044	3,280,000
	4,385,234	3,614,916
Less valuation allowance	(4,282,159)	(3,491,023)
	$ 103,075	$ 123,893

At March 31, 2005, we had U.S. net operating loss carryforwards (NOL) of approximately $10,857,000 for U.S. income tax purposes, which expire in 2012 through 2023, and NOL s in the U.K. of $148,471, which can be carried forward indefinitely. U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. In addition, U.S. tax rules impose limitations on the use of net operating losses 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.

A valuation allowance is provided when it is more likely than not a portion of the deferred tax assets will not be realized. We have established a valuation allowance for U.S. and certain foreign deferred tax assets due to the uncertainty that enough income will be generated in those taxing jurisdictions to utilize the assets. Therefore, we have not reflected any benefit of such net operating loss carryforwards in the accompanying financial statements. The deferred tax asset increased by $770,000 and $715,000, respectively in fiscal 2005 and 2004. The related valuation allowance increased by $791,000 and $715,000, respectively, in fiscal 2005 and 2004.

7. Business Segment Information

We sell Macroplastique®, a soft tissue bulking material, for the treatment of urinary incontinence. In addition, we market our soft tissue bulking material for additional indications, including for the treatment of vocal cord rehabilitation, fecal incontinence and soft tissue facial augmentation. At this time, we make sales only outside the United States. Our current objectives are to focus on obtaining U.S. regulatory approvals for Macroplastique for treating stress urinary incontinence, or SUI, on obtaining U.S. regulatory approvals for the Urgent PC device for treating overactive bladder, and on increasing market penetration and sales of Macroplastique for the treatment of SUI and vesicoureteral reflux and of PTQ Implants for the treatment of fecal incontinence in markets outside the U.S. We anticipate initiating marketing in the U.S. once we obtain the requisite approvals. The Macroplastique product line accounted for 76% and 81%, respectively, of total net sales during fiscal 2005 and 2004. In addition, we sell specialized wound care products in The Netherlands and United Kingdom as a distributor.

Based upon the above, we operate in only one reportable segment consisting of medical products primarily for the urology market.

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Information regarding operations in different geographies for the years ended March 31, 2005 and 2004 is as follows:

	United States	The Netherlands	United Kingdom	Adjustments and eliminations	Consolidated
Fiscal 2005					
Sales to customers	$	$ 5,612,250	$ 1,703,365	$ (657,889)	$ 6,657,726
Income tax expense		91,503			91,503
Net income (loss)	(1,855,416)	153,977	21,990	(55,316)	(1,734,765)
Long-lived assets at March 31, 2005	277,780	791,121	10,452		1,079,353
Fiscal 2004					
Sales to customers		4,776,292	1,524,953	(586,349)	5,714,896
Income tax expense		220,672		8,513	229,185
Net income (loss)	(1,808,753)	448,497	(26,970)	(124,067)	(1,511,293)
Long-lived assets at March 31, 2004	314,514	788,343	19,754		1,122,611

8. Subsequent Events

Warrants. As a result of our suspension of the exercise of the 706,218 warrants originally issued in July 2002, 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 this registration statement covering the shares underlying these warrants. In April 2005, we recognized a liability of $1.4 million associated with the grant of these new warrants. The value of these warrants has been determined using the Black-Scholes option-pricing model and we will continue to report in earnings any subsequent change in the fair value of this liability.

Private Placement. In April 2005, the Company conducted a private placement of common stock in which it sold 2,147,142 shares of common stock at a price per share of $3.50, together with warrants to purchase 1,180,928 shares of common stock, for an aggregate purchase price of approximately $7.5 million. The warrants are exercisable for five years at an exercise price of $4.75 per share. The company is obligated to file and obtain the effectiveness of a registration statement covering the resale of the shares sold in the private placement and the shares that may be acquired upon exercise of the warrants. These warrants will be accounted for as a liability until the above registration statement becomes effective. The Company was required to file this registration statement by May 21, 2005, but did not timely do so. The Company agreed to pay certain liquidated damages if the registration statement was not timely filed and if it was not effective by July 20, 2005. The company will record a liability in its financial statements beginning in the first quarter of fiscal 2006 for any liquidated damages incurred.

Dutch Pension Plan. We closed our Dutch defined benefit plan for new employees effective April 2005. As of that date, the Dutch subsidiary established a defined contribution plan.

9. Unaudited Subsequent to the Date of Independent Registered Public Account s Report

Legal Proceedings. On July 15, 2005, our former Vice President of Research and Development and Managing Director of our United Kingdom subsidiary, filed a petition in Dutch Court (Roermond). The petition requests the

Dutch court to terminate his employment agreement with us and made a claim for 528,058 (or approximately $636,000) in severance compensation as well as other damages. We opposed the petition and sought to pay no more than approximately $100,000 in total severance compensation under the employment agreement. In August 2005, the Dutch Court granted a total award to the former employee of 177,000 (or approximately $219,000). We do not plan to appeal this determination and will record the liability and related expense in the second quarter of fiscal 2006.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2005
Assets	
Current assets:	
Cash and cash equivalents	$ 6,958,238
Accounts receivable, net	920,824
Inventories	700,390
Income tax receivable	91,636
Other	248,105
Total current assets	8,919,193
Property, plant, and equipment, net	1,077,918
Intangible assets, net	289,676
Deferred tax assets	89,001
Total assets	$ 10,375,788

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2005
Liabilities and Shareholders Equity	
Current liabilities:	
Current maturities long-term debt	$ 41,616
Accounts payable	361,886
Accrued liabilities	613,220
Warrant liability	2,058,971
Total current liabilities	3,075,693
Long-term debt less current maturities	419,950
Accrued pension liability	302,919
Total liabilities	3,798,562
Shareholders equity:	
Common stock $.01 par value; 20,000,000 shares authorized, 6,846,739 and 4,699,597 shares issued and outstanding at June 30, 2005 and March 31, 2005, respectively	68,467
Additional paid-in capital	14,796,566
Accumulated deficit	(7,953,700)
Accumulated other comprehensive loss	(334,107)
Total shareholders equity	6,577,226
Total liabilities and shareholders equity	$ 10,375,788

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,	
	2005	2004
Net sales	$ 1,645,653	$ 1,752,496
Cost of goods sold	420,828	463,558
Gross profit	1,224,825	1,288,938
Operating expenses		
General and administrative	690,564	391,112
Research and development	630,598	580,053
Selling and marketing	664,033	527,957
	1,985,195	1,499,122
Operating loss	(760,370)	(210,184)
Other income (expense)		
Interest income	27,380	5,879
Interest expense	(4,809)	(5,184)
Warrant expense	(686,295)	
Foreign currency exchange loss	(1,199)	(9,411)
	(664,923)	(8,716)
Loss before income taxes	(1,425,293)	(218,900)
Income tax expense	37,020	66,459
Net loss	$ (1,462,313)	$ (285,359)
Basic and diluted loss per common share	$ (0.23)	$ (0.06)
Weighted average common shares outstanding:		
Basic and diluted	6,351,245	4,591,136

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENT OF SHAREHOLDERS EQUITY AND COMPREHENSIVE LOSS
Quarter ended June 30, 2005
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders Equity
Balance at March 31, 2005	4,699,597	$ 46,996	$ 9,366,644	$ (6,491,387)	$ (130,357)	$ 2,791,896
Reissuance of warrants			(1,372,676)			(1,372,676)
Private placement	2,147,142	21,471	7,493,526			7,514,997
Costs of private placement			(690,928)			(690,928)
Net loss				(1,462,313)		(1,462,313)
Translation adjustment					(208,159)	(208,159)
Additional pension liability					4,409	4,409
Total comprehensive loss						(1,666,063)
Balance at June 30, 2005	6,846,739	$ 68,467	$ 14,796,566	$ (7,953,700)	$ (334,107)	$ 6,577,226

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UROPLASTY, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Three Months Ended June 30, 2005 and 2004
(Unaudited)

	Three Months Ended June 30,	
	2005	**2004**
Cash flows from operating activities:		
Net loss	$ (1,462,313)	$ (285,359)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	54,319	40,822
Loss on disposal of assets		2,281
Warrant expense	686,295	
Deferred tax assets	7,453	16,220
Changes in operating assets and liabilities:		
Accounts receivable	(37,436)	38,924
Inventories	(222,364)	39,201
Other current assets	(92,228)	(15,511)
Accounts payable	11,650	(2,301)
Accrued liabilities	165,265	(16,849)
Accrued pension liability	19,613	(3,851)
Additional pension liability		1,824
Net cash used in operating activities	(869,746)	(184,599)
Cash flows from investing activities:		
Payments for property, plant and equipment	(129,474)	(38,748)
Payments for intangible assets	(266,667)	(2,656)
Net cash used in investing activities	(396,141)	(41,404)
Cash flows from financing activities:		
Repayment of long-term debt	(10,819)	(10,381)
Net proceeds from issuance of common stock	6,824,069	41,130
Net cash provided by financing activities	6,813,250	30,749
Effect of exchange rates on cash and cash equivalents	(81,809)	(214)
Net increase (decrease) in cash and cash equivalents	5,465,554	(195,468)

Cash and cash equivalents at beginning of period	1,492,684	2,697,670
Cash and cash equivalents at end of period	$ 6,958,238	$ 2,502,202
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	$ 5,056	$ 5,496
Cash paid during the period for income taxes	15,281	24,133

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES
Notes to the Condensed Interim Consolidated Financial Statements
(Unaudited)

1. Basis of Presentation

We have prepared our condensed consolidated financial statements included in this Form 10-QSB, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in the consolidated financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted, pursuant to such rules and regulations. The consolidated results of operations for any interim period are not necessarily indicative of results for a full year. These condensed consolidated statements should be read in conjunction with the consolidated financial statements and related notes included in our Annual Report on Form 10-KSB for the year ended March 31, 2005.

The condensed consolidated financial statements presented herein as of June 30, 2005 and for the three-month periods ended June 30, 2005 and 2004 reflect, in the opinion of management, all material adjustments consisting only of normal recurring adjustments necessary for a fair presentation of the consolidated financial position, results of operations and cash flows for the interim periods.

We have identified certain accounting policies that we consider particularly important for the portrayal of our results of operations and financial position and which may require the application of a higher level of judgment by our management, and as a result are subject to an inherent level of uncertainty. These are characterized as critical accounting policies and address revenue recognition, inventories, foreign currency translation and transactions, and impairment of long-lived assets, each of which is more fully described in our Annual Report on Form 10-KSB for the year ended March 31, 2005. Based upon our review, we have determined that these policies remain our most critical accounting policies for the three-month period ended June 30, 2005, and have made no changes to these policies during fiscal 2006.

2. Nature of Business and Corporate Liquidity

We currently sell our products outside of the United States and are pursuing regulatory approvals to market our products in the United States. We anticipate increasing our sales and marketing activities in the U.S. as we obtain such approvals. The FDA approval process can be costly, lengthy and uncertain.

In March 2005, we entered into a business loan agreement with Venture Bank, pursuant to which we may borrow up to $500,000 on a revolving basis. All amounts which the bank advances to us are due in March 2006, unless the bank renews the agreement. Amounts advanced to us accrue interest at a variable rate of 1% in excess of the published prime rate in the Wall Street Journal, with a minimum rate of 6% per annum. We are obligated to pay interest monthly on the outstanding principal balance. Advances under this agreement are secured by substantially all our assets. At June 30, 2005 we had no outstanding balance under the agreement.

In April 2005, we conducted a private placement of common stock 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 common stock, for an aggregate purchase price of approximately $7.5 million. The stock sale proceeds are offset by costs of approximately $700,000, resulting in net proceeds of approximately $6.8 million. The warrants are exercisable for five years at an exercise price of $4.75 per share.

We believe that our current resources, funds generated from sale of our products outside the U.S. along with existing bank arrangements and the proceeds received from the recently completed private placement will be adequate to meet our cash flow needs, including regulatory activities associated with existing products, through fiscal 2006. Ultimately, we will need to achieve profitability and positive cash flows from operations to fund our operations and grow our business beyond fiscal 2006.

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3. Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value) and consist of the following:

	June 30, 2005
Raw materials	$ 302,901
Work-in-process	121,735
Finished goods	275,754
	$ 700,390

4. Intangible Assets

Intangible assets are comprised of patents, trademarks and licensed technology which are amortized on a straight-line basis over their estimated useful lives or contractual terms, whichever is less.

		June 30, 2005		
	Estimated Lives (Years)	Gross Carrying Amount	Accumulated Amortization	Net value
Licensed technology	5	$ 292,957	$ 33,051	$ 259,906
Patents and inventions	6	237,900	208,130	29,770
Totals		$ 530,857	$ 241,181	$ 289,676

Estimated annual amortization for these assets for the years ended March 31, are as follows:

Remainder of 2006	$ 48,275
2007	59,656
2008	59,091
2009	58,987
2010	56,704
Thereafter	6,963
	$ 289,676

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5. Comprehensive Loss

Comprehensive loss consists of net loss, and the translation adjustments as follows:

	Three Months Ended June 30,	
	2005	**2004**
Net loss	$ (1,462,313)	$ (285,359)
Items of other comprehensive income (loss):		
Translation adjustment	(208,159)	(23,572)
Additional pension liability	4,409	941
Comprehensive loss	$ (1,666,063)	$ (307,990)

6. Reconciliation of Net Loss and Per Share Amounts Used in EPS Calculation

Basic and diluted loss per common share is calculated by dividing net loss by the weighted-average common shares outstanding during the period.

	Basic and Diluted Loss Per Share
For the three months ended:	
June 30, 2005 Net loss	$ (1,462,313)
Weighted average shares	6,351,245
Per share amount	$ (0.23)
For the three months ended:	
June 30, 2004	
Net loss	$ (285,359)
Weighted average shares	4,591,136
Per share amount	$ (0.06)

The following options and warrants outstanding at June 30, 2005 and 2004 to purchase shares of common stock were excluded from diluted loss per share, because of their anti-dilutive effect:

	Number of Options/Warrants	**Range of Exercise Prices**
For the three months ended:		
June 30, 2005	3,706,338	$0.90 to $10.50
June 30, 2004	1,710,069	$0.90 to $10.50

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7. Shareholders Equity

We apply the intrinsic-value method to account for employee stock-based compensation. As such, compensation expense, if any, is recorded on the date of grant if the current market price of the underlying stock exceeds the exercise price.

We account for stock-based instruments granted to non-employees under the fair value method of SFAS No. 123 and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Under SFAS No. 123, we record options at their fair value on the measurement date, which is typically the vesting date.

Consulting Agreements

On April 1, 2003, we executed a consulting agreement with CCRI Corporation (CCRI) to provide investor relations and development services. We pay CCRI a monthly fee of $4,000 plus expenses. CCRI received 35,000 shares of fully vested restricted common stock, and vested warrants to purchase 50,000 shares of common stock at an exercise price of $3.00 per share, and received vested warrants to purchase 50,000 shares of common stock at an exercise price of $5.00 per share on November 2, 2003. We fully amortized the fair value of the common stock and warrants in fiscal 2004. On April 1, 2005, we extended the agreement for one year. The monthly fee of $4,000 plus expenses remained the same.

Warrants

As a result of our suspension of the exercise of the 706,218 warrants originally issued in July 2002, 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 this registration statement covering the shares underlying these warrants. In April 2005, we recognized a liability of $1.4 million associated with the grant of these new warrants. The value of these warrants has been determined using the Black-Scholes option-pricing model. We reported additional expense of approximately $686,000 in the first quarter due to the increase in the fair value of these warrants from their date of issue through June 30, 2005. This fair value adjustment will be continued until such time as the warrants are exercised or expire.

8. Stock-based Compensation

Had we determined compensation cost based on the fair value at the grant date for our stock options issued to employees under SFAS 123, Accounting for Stock-Based Compensation, our net loss and per share amounts would have increased to the pro forma amounts shown below:

	Three Months Ended June 30,	
	2005	**2004**
Net loss As reported	$ (1,462,313)	$ (285,359)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(433,431)	(36,007)
Net loss Pro forma	$ (1,895,744)	$ (321,366)
Net loss per common share As reported: Basic and diluted	$ (0.23)	$ (0.06)
Net loss per common share Pro forma: Basic and diluted	$ (0.30)	$ (0.07)

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9. Savings and Retirement Plans

We sponsor various plans for eligible employees in the United States, the United Kingdom (UK), and The Netherlands. Our retirement savings plan in the United States conforms to Section 401(k) of the Internal Revenue Code and participation is available to substantially all employees. We may also make discretionary contributions ratably to all eligible employees. We made no contributions in association with these plans in the United States for the quarters ended June 30, 2005 and 2004, respectively.

Our international subsidiaries have defined benefit retirement plans for eligible employees. These plans provide benefits based on each employee s years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. Pension plan assets are invested in insurance contracts. The defined benefit plan in The Netherlands is closed for new employees effective April 2005. As of that date, the Dutch subsidiary established a defined contribution plan. We froze our UK subsidiary s defined benefit plan on December 31, 2004. On March 10, 2005, the UK subsidiary established a defined contribution plan.

The cost for our plan in The Netherlands includes the following components for the periods ended June 30, 2005 and 2004:

	Three Months Ended June 30,	
	2005	**2004**
Gross service cost, net of employee contribution	$ 44,861	$ 34,033
Interest cost	25,835	21,412
Expected return on assets	(14,911)	(13,486)
Amortization	7,267	13,702
Net periodic retirement cost	$ 63,052	$ 55,661

Major assumptions used in the above calculations include:

	Three Months Ended June 30,	
	2005	**2004**
Discount rate	4.50-5.25%	5.25-5.50%
Expected return on assets	4.00-5.00%	4.50-5.00%
Expected rate of increase in future compensation		
General	3%	3%
Individual	0%-3%	0%-3%

10. Foreign Currency Translation

We translate all assets and liabilities using period-end exchange rates. 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 our consolidated statements of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders equity.

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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 intercompany obligations between us and our foreign subsidiaries. All intercompany balances are revolving in nature and are not deemed to be long-term balances. For the three-months ended June 30, 2005 and 2004, we recognized foreign currency losses of $1,199 and $9,411, respectively.

11. Income Tax Expense

During the quarters ended June 30, 2005 and 2004, our Dutch subsidiaries recorded income tax expense of $37,020 and $66,459, respectively, as we have fully utilized our net operating loss carryforwards. We cannot use our U.S. net operating loss carryforwards to offset taxable income in foreign jurisdictions.

12. Business Segment Information

We sell Macroplastique®, a soft tissue bulking material, for the treatment of urinary incontinence. In addition, we market our soft tissue bulking material for additional indications, including for the treatment of vocal cord rehabilitation, fecal incontinence and soft tissue facial augmentation. At this time, we make sales only outside the United States. Our current objectives are to focus on obtaining U.S. regulatory approvals for Macroplastique for treating stress urinary incontinence, or SUI, on obtaining U.S. regulatory approvals for the Urgent PC device for treating overactive bladder and on increasing market penetration and sales of Macroplastique for the treatment of SUI and vesicoureteral reflux and of PTQ Implants for the treatment of fecal incontinence in markets outside the U.S. We anticipate marketing in the U.S. with requisite approvals. The I-Stop recently received FDA 510(k) clearance and we are initiating a U.S. sales launch. The Macroplastique product line accounted for 70% and 79% of total net sales for the three-months ended June 30, 2005 and 2004, respectively. In addition, we sell specialized wound care products in The Netherlands and United Kingdom as a distributor.

Based upon the above, we operate in only one reportable segment consisting of medical products primarily for the urology market.

Information regarding operations in different geographies for the three-months ended June 30, 2005 and 2004 is as follows:

	United States	The Netherlands	United Kingdom	Adjustments and Eliminations	Consolidated
Fiscal 2006					
Sales to customers, three-months ended June 30, 2005	$	$ 1,337,601	$ 457,770	$ (149,718)	$ 1,645,653
Income tax expense, three-months ended June 30, 2005		37,020			37,020
Net income (loss), three-months ended June 30, 2005	(1,656,475)	(12,104)	44,414	161,852	(1,462,313)
Long-lived assets at June 30, 2005	619,125	741,071	7,398		1,367,594
Fiscal 2005					
Sales to customers, three-months ended June 30, 2004		1,445,453	459,831	(152,788)	1,752,496

Income tax expense, three-months ended June 30, 2004		66,459			66,459
Net income (loss), three-months ended June 30, 2004	(554,046)	133,251	14,332	121,104	(285,359)
Long-lived asset at June 30, 2004	327,924	767,538	17,643		1,113,105

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PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 24. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Minnesota Statutes Section 302A.521 provides that a corporation shall indemnify any person made or threatened to be made a party to a proceeding by reason of the former or present official capacity of such person against judgments, penalties, fines (including, without limitation, excise taxes assessed against such person with respect to any employee benefit plan), settlements and reasonable expenses, including attorneys fees and disbursements, incurred by such person in connection with the proceeding, if, with respect to the acts or omissions of such person complained of in the proceeding, such person (1) has not been indemnified therefor by another organization or employee benefit plan; (2) acted in good faith; (3) received no improper personal benefit and Section 302A.255 (with respect to director conflicts of interest), if applicable, has been satisfied; (4) in the case of a criminal proceeding, had no reasonable cause to believe the conduct was unlawful; and (5) reasonably believed that the conduct was in the best interests of the corporation in the case of acts or omissions in such person s official capacity for the corporation or reasonably believed that the conduct was not opposed to the best interests of the corporation in the case of acts or omissions in such person s official capacity for other affiliated organizations. Our Bylaws provide that we shall indemnify officers and directors to the extent permitted by Section 302A.521.

ITEM 25. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the costs and expenses payable by us in connection with the registration of the common stock hereunder. All amounts are estimated, except for the SEC registration fee.

Item	Amount
SEC registration fee	$ 213
Accountants fees and expenses	20,000
Legal fees and expenses	30,000
Printing expenses	5,000
Blue sky fees and expenses	
Transfer Agent and Registrar fees and expenses	
Miscellaneous	787
Total	$ 56,000

ITEM 26. RECENT SALES OF UNREGISTERED SECURITIES

The following is a list of our securities sold within the past three years without registration under the Securities Act:

(1) We issued and sold an aggregate of 2,147,142 shares of common stock, as well as five-year warrants exercisable at $4.75 per share to purchase 1,180,928 shares of common stock, for an aggregate consideration of approximately $7.5 million. The securities were sold pursuant to a securities purchase agreement dated April 21, 2005.

(2) In January 2005, we granted options to purchase 400,000 shares of common stock to Sam B. Humphries pursuant to an employment agreement, and options to purchase 100,000 shares of common stock to Daniel G. Holman pursuant to an employment and consulting agreement. The exercise price of these options is $5.19 per share.

(3) In December 2004, we granted to directors options to purchase an aggregate of 150,000 shares of common stock at an exercise price of $5.30 per share.

(4) In April 2003, we granted to a director options to purchase 30,000 shares of common stock at an exercise price of $2.25 per share, and to Executive Advisory Group, as partial consideration for consulting services, options to purchase 50,000 shares of common stock at an exercise price of $2.80 per share.

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(5) In April 2003, we issued 35,000 shares of common stock and warrants to purchase 50,000 shares of common stock at an exercise price of $3.00 per share to CCRI Corporation for consulting services rendered. Also, in November 2003, we issued warrants to purchase 50,000 shares of common stock at an exercise price of $5.00 per share to CCRI.

There were no underwriters employed in connection with any of the transactions set forth in this Item 26.

Each of the option and warrant grants and stock issuances was deemed exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act. The recipients of securities represented that they were accredited investors and that their intentions were to acquire the securities for investment only and not with a view to or for distributing or reselling such securities, and appropriate legends were affixed to the share certificates and other instruments issued in such transactions. All recipients either received adequate information about us or had access to such information. The sales of these securities were made without general solicitation or advertising.

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ITEM 27. EXHIBITS

Number	Description
2.1	First Amended Joint Plan of Reorganization (Modified) dated January 31, 1994 (Incorporated by reference to Exhibit 8.1 to Registrant s Registration Statement on Form 10SB)
3.1	Articles of Incorporation of Uroplasty, Inc. (Incorporated by reference to Exhibit 2.1 to Registrant s Registration Statement on Form 10SB)
3.2	Bylaws of Uroplasty, Inc. (Incorporated by reference to Exhibit 2.2 to Registrant s Registration Statement on Form 10SB)
4.1	Form of Stock Certificate representing shares of our Common Stock (Incorporated by reference to Exhibit 3.1 to Registrant s Registration Statement on Form 10SB)
4.2*	Form of Warrant
5*	Legal Opinion of Messerli & Kramer P.A.
10.1	Settlement Agreement and Release dated November 30, 1993 by and between Bioplasty, Inc., Bio-Manufacturing, Inc., Uroplasty, Inc., Arthur A. Beisang, Arthur A. Beisang III, MD and Robert A. Ersek, MD (Incorporated by reference to Exhibit 6.1 to Registrant s Registration Statement on Form 10SB)
10.2	Purchase and Sale Agreement dated December 1, 1995 by and among Bio-Vascular, Inc., Bioplasty, Inc., and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.2 to Registrant s Registration Statement on Form 10SB)
10.3	License Agreement dated December 1, 1995 by and between Bio-Vascular, Inc. and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.3 to Registrant s Registration Statement on Form 10SB)
10.4	Lease Agreement dated January 10, 1995 between Summer Business Center Partnership and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.4 to Registrant s Registration Statement on Form 10SB)
10.5	Unsecured $640,000 Promissory Note dated March 30, 1994 by and between Bioplasty, Inc., Uroplasty, Inc. and Bioplasty Product Claimants Trust (Incorporated by reference to Exhibit 6.5 to Registrant s Registration Statement on Form 10SB)
10.6	Agreement and Satisfaction dated January 30, 1995 by and between Bioplasty Product Claimants Trust and Bioplasty, Inc. (Incorporated by reference to Exhibit 6.6 to Registrant s Registration Statement on Form 10SB)
10.7	Asset Sale and Satisfaction of Debt Agreement dated June 23, 1995 by and between Bioplasty, Inc. and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.7 to Registrant s Registration Statement on Form 10SB)
10.8	Executory Contract Assumption Stipulation dated December 28, 1993 by and between Bioplasty, Inc., Uroplasty, Inc., and Collagen Corporation (Incorporated by reference to Exhibit 6.8 to Registrant s Registration Statement on Form 10SB)

10.9	Settlement and License Agreement dated July 23, 1992 by and between Collagen Corporation, Bioplasty, Inc., and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.9 to Registrant s Registration Statement on Form 10SB)
10.10	Employment Agreement between Uroplasty, Inc. and Christopher Harris dated December 7, 1999. (Incorporated by reference to Exhibit 10.11 to Registrant s Form 10-KSB for the year ended 03-31-2000.)
10.11	Employment Agreement between Uroplasty, Inc. and Susan Holman dated December 7, 1999. (Incorporated by reference to Exhibit 10.13 to Registrant s Form 10-KSB for the year ended 03-31-2000.)
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23.2*	Consent of KPMG LLP

23.3* Consent of Messerli & Kramer P.A. (included in Exhibit 5)

24.1* Power of Attorney (included on signature page)

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ITEM 28. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective Registration Statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement,

provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the Registration Statement in on Form S-3, Form S-8 or Form F-3, and the information required to be included in the post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Registration Statement.

(2) That, for purposes of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this Registration Statement on Form SB-2 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Minneapolis, State of Minnesota, on September 14, 2005.

UROPLASTY, INC.

By: /s/ SAM B. HUMPHRIES
Sam B. Humphries
President and Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints and hereby authorizes each of Sam B. Humphries and Daniel G. Holman such person s true and lawful attorney-in-fact, with full power of substitution or resubstitution, for such person and in such person s name, place and stead, in any and all capacities, to sign on such person s behalf, individually and in each capacity stated below, any and all amendments, including post-effective amendments to this registration statement, and to sign any and all additional registration statements relating to the same offering of securities as this registration statement that are filed pursuant to Rule 462(b) of the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	**Title/Capacity**	**Date**
/s/ SAM B. HUMPHRIES Sam B. Humphries	President, Chief Executive Officer and Director (Principal Executive Officer)	September 14, 2005
/s/ DANIEL G. HOLMAN Daniel G. Holman	Chairman and Chief Financial Officer (Principal Financial Officer)	September 14, 2005
/s/ ARIE J. KOOLE Arie J. Koole	Controller (Principal Accounting Officer)	September 14, 2005
/s/ JOEL R. PITLOR Joel R. Pitlor	Director	September 14, 2005
/s/ R. PATRICK MAXWELL R. Patrick Maxwell	Director	September 14, 2005
/s/ THOMAS E. JAMISON Thomas E. Jamison	Director	September 14, 2005

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EXHIBITS

Number	Description
2.1	First Amended Joint Plan of Reorganization (Modified) dated January 31, 1994 (Incorporated by reference to Exhibit 8.1 to Registrant s Registration Statement on Form 10SB)
3.1	Articles of Incorporation of Uroplasty, Inc. (Incorporated by reference to Exhibit 2.1 to Registrant s Registration Statement on Form 10SB)
3.2	Bylaws of Uroplasty, Inc. (Incorporated by reference to Exhibit 2.2 to Registrant s Registration Statement on Form 10SB)
4.1	Form of Stock Certificate representing shares of our Common Stock (Incorporated by reference to Exhibit 3.1 to Registrant s Registration Statement on Form 10SB)
4.2*	Form of Warrant
5*	Legal Opinion of Messerli & Kramer P.A.
10.1	Settlement Agreement and Release dated November 30, 1993 by and between Bioplasty, Inc., Bio-Manufacturing, Inc., Uroplasty, Inc., Arthur A. Beisang, Arthur A. Beisang III, MD and Robert A. Ersek, MD (Incorporated by reference to Exhibit 6.1 to Registrant s Registration Statement on Form 10SB)
10.2	Purchase and Sale Agreement dated December 1, 1995 by and among Bio-Vascular, Inc., Bioplasty, Inc., and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.2 to Registrant s Registration Statement on Form 10SB)
10.3	License Agreement dated December 1, 1995 by and between Bio-Vascular, Inc. and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.3 to Registrant s Registration Statement on Form 10SB)
10.4	Lease Agreement dated January 10, 1995 between Summer Business Center Partnership and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.4 to Registrant s Registration Statement on Form 10SB)
10.5	Unsecured $640,000 Promissory Note dated March 30, 1994 by and between Bioplasty, Inc., Uroplasty, Inc. and Bioplasty Product Claimants Trust (Incorporated by reference to Exhibit 6.5 to Registrant s Registration Statement on Form 10SB)
10.6	Agreement and Satisfaction dated January 30, 1995 by and between Bioplasty Product Claimants Trust and Bioplasty, Inc. (Incorporated by reference to Exhibit 6.6 to Registrant s Registration Statement on Form 10SB)
10.7	Asset Sale and Satisfaction of Debt Agreement dated June 23, 1995 by and between Bioplasty, Inc. and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.7 to Registrant s Registration Statement on Form 10SB)
10.8	Executory Contract Assumption Stipulation dated December 28, 1993 by and between Bioplasty, Inc., Uroplasty, Inc., and Collagen Corporation (Incorporated by reference to Exhibit 6.8 to Registrant s Registration Statement on Form 10SB)

10.9	Settlement and License Agreement dated July 23, 1992 by and between Collagen Corporation, Bioplasty, Inc., and Uroplasty, Inc. (Incorporated by reference to Exhibit 6.9 to Registrant s Registration Statement on Form 10SB)
10.10	Employment Agreement between Uroplasty, Inc. and Christopher Harris dated December 7, 1999. (Incorporated by reference to Exhibit 10.11 to Registrant s Form 10-KSB for the year ended 03-31-2000.)
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