UROPLASTY INC
Form SB-2/A
April 27, 2006

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As filed with the Securities and Exchange Commission on April 27, 2006
Registration No. 333-133072

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

AMENDMENT NO. 1
TO
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)

Daniel G. Holman
Interim 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

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.

COMBINED WITH FORM SB-2 REGISTRATION STATEMENT
REGISTRATION NO. 333-126737
(JULY 20, 2005) PURSUANT TO RULE 429(A)

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EXPLANATORY NOTE

The prospectus contained in this Registration Statement is a combined prospectus under Rule 429(a) of the Securities Act of 1933, as amended, (the Act) and relates to the registration statement on Form SB-2 (Registration No. 333-126737) filed by Uroplasty, Inc. with the Securities and Exchange Commission, including any exhibits thereto, on July 20, 2005 and declared effective by the Securities Exchange Commission on July 29, 2005. In accord with Rule 429(b) of the Act, this registration statement shall act, upon effectiveness, as a post-effective amendment to Registration Statement No. 333-126737. The registration statement registered 2,147,142 shares of our common stock (285,714 shares of which have since been sold) and 1,180,928 shares of our common stock issuable upon the exercise of warrants on behalf of the shareholders identified in the registration statement as selling shareholders (the Selling Shareholders). The purpose of this registration statement is to register 57,381 additional shares of our common stock issued in February 2006 to the Selling Shareholders in connection with certain rights they had pursuant to the Registration Rights Agreement dated April 22, 2005 between us and the selling shareholders named therein. We are registering the additional shares for resale by the Selling Shareholders.

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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 April 27, 2006.

PROSPECTUS

UROPLASTY, INC.
1,918,809 Shares of Common Stock
and
1,180,928 Shares of Common Stock
Issuable Upon the Exercise of Warrants

This prospectus relates to shares of our common stock that may be sold at various times by the selling shareholders identified under Principal and Selling Shareholders. We will not receive any proceeds from the sale of those shares. Our common stock is traded on the American Stock Exchange under the symbol UPI. On April 26, 2006, the closing price of our common stock on the American Stock Exchange was $2.28 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 April , 2006

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

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PROSPECTUS SUMMARY

This summary highlights the key information contained in this prospectus. Because it is a summary, it does not contain all the information you should consider before investing in our common stock. You should read carefully this entire prospectus. In particular, you should read the section entitled Risk Factors and the consolidated financial statements and the notes relating to those statements included elsewhere in this prospectus. The references in this prospectus to we, our, or us refer to Uroplasty, Inc. and its subsidiaries, unless the context indicates otherwise.

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. Our Macroplastique products have not yet been cleared for marketing in the United States.

Products we market 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. In August 2005 this product 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 received regulatory approvals for sale of this product in the United States and Canada in October 2005, and in Europe in November 2005. Subsequently, we have launched the product for sale in those markets.

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 product line;
- Build our own United States sales and marketing organization, using a combination of direct and independent sales representatives;
- 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, which we expect will delay possible approval of Macroplastique until late in Fiscal 2007. We will incur substantial expenses in connection with these regulatory activities. 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 have established a direct sales force in the United States to commercialize the I-Stop tape and the UrgentÒ PC neuromodulation system. We anticipate increasing our sales and marketing organization in the United States.

Our company was incorporated in Minnesota in 1992. Our headquarters are currently 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

Common stock offered by selling shareholders:	Up to 1,918,809 shares of common stock and 1,180,928 shares of common stock issuable upon the exercise of warrants.
Use of proceeds:	We will not receive any proceeds from the sale of shares in this offering.
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.
Trading symbol:	Our common stock is traded on the American Stock Exchange under the symbol UPI.

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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 nine months ended December 31, 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:

	Nine Months Ended December 31,		Fiscal Year Ended March 31,	
	2005	2004	2005	2004
	(unaudited)			
Net sales	$ 4,793,134	$ 5,012,912	$ 6,657,726	$ 5,714,896
Cost of goods sold	1,274,308	1,317,303	1,755,456	1,452,331
Gross profit	3,518,826	3,695,609	4,902,270	4,262,565
General and administrative expenses	2,294,752	1,403,762	2,260,240	2,069,568
Research and development expenses	2,361,609	1,724,488	2,258,127	1,820,690
Selling and marketing expenses	2,321,122	1,535,642	2,015,655	1,714,475
	6,977,483	4,663,892	6,534,022	5,604,733
Operating loss	(3,458,657)	(968,283)	(1,631,752)	(1,342,168)
Warrant benefit	575,471			
Interest income	107,507	23,093	30,168	30,173
Interest expense	(22,091)	(15,682)	(25,934)	(21,995)
Foreign currency exchange gain (loss)	(15,779)	(20,564)	(15,744)	45,882
Other	438			6,000
Loss before income taxes	(2,813,111)	(981,436)	(1,643,262)	(1,282,108)
Income tax expense	42,648	138,540	91,503	229,185
Net loss	$ (2,855,759)	$ (1,119,976)	$ (1,734,765)	$ (1,511,293)
Basic and diluted net loss per common share	$ (0.43)	$ (0.24)	$ (0.37)	$ (0.33)
Basic and diluted weighted average common shares	6,695,674	4,638,628	4,651,732	4,517,979

Consolidated Balance Sheet Data:

	December 31, 2005	March 31, 2005	2004

	(unaudited)		
Cash and cash equivalents	$ 2,532,823	$1,492,684	$2,697,670
Short-term investments	1,526,214		
Working capital	4,150,418	2,374,514	3,671,919
Property, plant and equipment, net	1,032,196	1,040,253	1,071,116
Total assets	7,582,881	4,443,224	5,763,558
Long-term debt, less current portion	390,665	461,265	479,720
Shareholders equity	4,988,325	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 December 31, 2005, we had an accumulated deficit of approximately $9.3 million primarily as a result of costs relating to the development, including seeking regulatory approvals, and commercialization of our Macroplastique, I-Stop tape, Urgent® PC neuromodulation system and related products. We expect our operating expenses relating to sales and marketing activities and product development, including seeking United States regulatory approval for 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 Macroplastique, and our ability to achieve widespread market acceptance for our products, which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

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 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. We will incur substantial expenses in connection with these regulatory activities. 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 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.

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.

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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.

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.

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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.

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

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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 our distribution in the United States and the United Kingdom. If CL Medical experiences manufacturing and control problems or delays, we may not have the I-Stop product manufactured and delivered in a timely manner. This would limit our ability to generate revenues.

The loss or interruption of materials from any of our key suppliers could slow down the manufacture of our products 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.

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.

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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, and will need to raise additional debt or equity financing to expand our sales and marketing organizations. 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.

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

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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;

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;

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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.

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.

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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.

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:

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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 senior management team and other key personnel, we may not be able to manage our operations and meet our strategic objectives.

Our future success depends, in large part, on the continued service of our senior management. Continuation of our senior management is integral to our future success, based on their significant expertise and knowledge of our business and products. We have no key person insurance with respect to any of our senior managers, and any loss or interruption of their services could significantly reduce our ability to effectively manage our operations and implement our strategy. Also, we depend on the continued service of other key 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 for our Macroplastique product line;

the timing and cost involved in manufacturing scale-up and in establishing sales, marketing and distribution capabilities in the United States 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.

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.

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Risks Relating to this Offering

You may be unable to sell your investment.

In general, there has been little trading activity in our common stock. The relatively small trading volume may make it difficult for investors to sell their shares.

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, prior to the post-effective amendment covered by this registration statement, 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). After this post effective amendment is filed, the aggregate number of shares covered by this registration statement will increase to 3,385,451 common shares. In addition, we have filed a registration statement (Registration No. 333-128313) under the Securities Act covering the issuance of up to 806,218 shares of common stock that existing security holders may acquire upon the exercise of outstanding warrants. The registration statement has not yet been declared effective therefore these shares are currently not freely tradeable. 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. In addition, after shareholder approval of our 2006 Stock and Incentive Option Plan, we also intend to register 1.2 million shares of our common stock for future issuance under that plan. As of March 17, 2006, 1,799,227 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.

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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 obligations, or result in material misstatements in our consolidated financial statements.

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, 2008 deadline, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations 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