UROPLASTY INC
Form 424B4
December 21, 2006

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Registration No. 333-138265

PROSPECTUS

2,430,000 SHARES

Common Stock

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

Our common stock is traded on the American Stock Exchange under the symbol UPI. On December 20, 2006, the closing price of our common stock on the American Stock Exchange was $2.40 per share.

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

	Per Share	Total
Public offering price	$ 2.00	$ 4,860,000
Agent fees and commissions	$ .12	$ 291,600
Proceeds to Uroplasty before expenses	$ 1.88	$ 4,568,400

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

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

Craig-Hallum Capital Group LLC

Prospectus dated December 21, 2006

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

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PROSPECTUS SUMMARY

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

Overview

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

Market

Voiding dysfunctions affect urinary or fecal control and can result in unwanted leakage (urinary or fecal incontinence) or uncontrolled bladder sensations (overactive bladder). The Agency for Health Care Policy and Research (AHCPR), a division of the Public Health Service, U.S. Department of Health and Human Services, estimates that urinary incontinence affects about 13 million people in the United States, of which 85% (11 million) are women. AHCPR estimates the total cost of treating incontinence (management and curative approaches) of all types in the United States as $16 billion. Overactive bladder (OAB) is a prevalent and challenging urologic problem affecting an estimated 34 million Americans. Historically, only a small percentage of the patients suffering from these disorders have sought treatment. In recent years, however, the number of people seeking treatment has grown as a result of the publicity associated with new minimally invasive treatment alternatives.

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

Strategy

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

Focus on office-based solutions for physicians.

Grow our United States sales and international distribution.

Educate physicians and patients about the benefits of Urgent PC.

Provide patient-driven alternatives.

Develop, license or acquire new products.

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Our Products

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

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

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

Sales and Marketing

We are focusing our sales and marketing efforts primarily on office-based and outpatient surgery-based urologists, urogynecologists and gynecologists with significant patient volume. We believe the United States is a significant opportunity for future sales of our products. In order to grow our United States business, we recently established a sales organization, consisting of a direct field sales management team and independent sales representatives, and a marketing organization to market our products directly to our customers. By expanding our United States presence, we intend to develop long-standing relationships with leading physicians treating incontinence and overactive bladder symptoms.

Corporate Information

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

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

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The Offering

Common stock offered:	Up to 2,430,000 shares.
Common stock outstanding before offering:	8,411,188 shares as of October 9, 2006.
Common stock to be outstanding after offering:	10,841,188 shares, assuming all of the shares offered are sold.
Use of proceeds:	We expect to use the net proceeds from this offering to fund operations and for working capital purposes. Our management will have broad discretion in determining the specific timing and uses of the offering proceeds.
Risk factors:	Our business is subject to a number of risks which you should consider before investing in our company. For a discussion of the significant risks associated with our business, please read the section entitled Risk Factors beginning on page 5.
Trading symbol:	Our common stock is traded on the American Stock Exchange under the symbol UPI.

The number of shares of common stock outstanding as of October 9, 2006 and to be outstanding after this offering exclude:

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

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

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

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Summary Financial Data

The following tables present our summary consolidated financial data for our fiscal years ended March 31, 2006 and 2005, which have been derived from our audited consolidated financial statements. The financial data for our six months ended September 30, 2006 and 2005 have been derived from our unaudited consolidated financial statements which, in management s opinion, have been prepared on the same basis as the audited consolidated financial statements and include all normal and recurring adjustments and accruals necessary for a fair presentation of such information. You should read this information in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

Consolidated Statements of Operations Data:

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

Consolidated Balance Sheet Data:

	March 31,	
	2006	2005

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

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risk factors set forth below and all other information contained in this prospectus before purchasing our common stock. If the following risks actually occur, our business, financial condition and results of operations could be seriously harmed, the price of our common stock could decline and you could lose part or all of your investment.

Risks Relating to Our Company and Industry

We continue to incur losses and may never reach profitability

We have incurred net losses in each of the last six fiscal years. As of September 30, 2006, we had an accumulated deficit of approximately $14.4 million primarily as a result of costs relating to the development, including seeking regulatory approvals, and commercialization of our Macroplastique, I-Stop sling, Urgent PC neuromodulation system and related products. We expect our operating expenses relating to sales and marketing activities and product development will continue to increase during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability to achieve widespread market acceptance for our products, which we cannot guarantee will happen. We may never realize significant revenue from the sale of our products or be profitable.

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

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

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

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

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

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

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

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

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

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

withdrawing or denying approvals or clearances for our products.

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

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

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

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

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

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

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

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

divert the attention of our management; or

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

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

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If we are unable to adequately protect our intellectual property rights, we may not be able to compete effectively and we may not be profitable.

Our success depends in part on our ability to protect our proprietary rights to the technologies used in our products. We rely on patent protection, as well as a combination of trademark laws and confidentiality, noncompetition and other contractual arrangements to protect our proprietary technology. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our patents and patent applications if issued, may not be broad enough to prevent competitors from introducing similar products into the market. Our patents, if challenged or if we attempt to enforce them, may not necessarily be upheld by the courts of any jurisdiction. In addition, patent protection in foreign countries may be different from patent protection under United States laws and may not be favorable to us. As a result, we may not be able to compete effectively.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- we may be unable to integrate the acquired business successfully and realize anticipated economic, operational and other benefits in a timely manner;
- the acquisition may disrupt our ongoing business, distract our management and divert our resource; and
- we may not have or be able to secure adequate financing to develop or maintain the acquired business.

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

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

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

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

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

We currently derive substantially all of our net sales from operations in international markets. We expect non-United States sales to continue to represent a significant portion of our revenues until we achieve sufficient market acceptance from United States customers of our FDA-approved products. The sale and shipping of our products and services across international borders, as well as the purchase of components and products from international sources, subject us to extensive United States and foreign governmental trade

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

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

- the imposition of additional United States and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export licensing requirements;
- the imposition of United States and international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- political and economic instability;
- fluctuations in the value of the U.S. dollar relative to foreign currencies;
- a shortage of high-quality sales people and distributors;
- loss of any key personnel that possess proprietary knowledge, or who are otherwise important to our success in certain international markets;
- changes in third-party reimbursement policies that may require some of the patients who receive our products to directly absorb medical costs or that may necessitate the reduction of the selling prices of our products;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- the imposition of restrictions on the activities of foreign agents, representatives and distributors;
- scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us;
- international pricing pressure;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- difficulties in enforcing or defending intellectual property rights; and

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

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

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