UROPLASTY INC
Form POS AM
November 19, 2007

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**As filed with the Securities and Exchange Commission on November 19, 2007**

**Registration No. 333-146787**

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

**POST-EFFECTIVE 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.)* |

**5420 Feltl Road**
**Minnetonka, Minnesota 55343**
**Telephone: (952) 426-6140**
*(Address, including zip code and telephone number, including area code, of Registrant s principal executive offices)*

**David B. Kaysen**
**President and Chief Executive Officer**
**5420 Feltl Road**
**Minnetonka, Minnesota 55343**
**Telephone: (952) 426-6140**
*(Name, address, including zip code and telephone number, including area code, of agent for service)*

***Copies to:***

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

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.**

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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 statement 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 NOVEMBER 19, 2007**

**PROSPECTUS**

**1,250,000 SHARES**

**Common Stock**

We are selling 1,250,000 shares of common stock. Our common stock is traded on the American Stock Exchange under the symbol UPI. On November 16, 2007, the closing price of our common stock on the American Stock Exchange was $3.85 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 | $ | $ |
| Underwriting commission | $ | $ |
| Proceeds to Uroplasty before expenses | $ | $ |

We have granted the underwriters a 30-day option to purchase up to an additional 187,500 shares of common stock to cover over-allotments, if any.

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

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

**Craig-Hallum Capital Group** **Noble International Investments, Inc.**

Prospectus dated , 2007

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

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## PROSPECTUS SUMMARY

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

### Overview

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

### Market

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

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

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

### Our Strategy

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

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

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

Build patient awareness of office-based solutions

Focus on office-based solutions for physicians.

Increase market coverage in the United States sales and internationally.

Develop, acquire or license new products.

**Our Products**

The Urgent PC neurostimulation system is a minimally invasive device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. The Urgent PC system uses percutaneous tibial nerve stimulation to deliver an electrical pulse that travels to the sacral nerve plexus, a control center for bladder function. We have received regulatory approvals for sale of the Urgent PC system in the United States, Canada and Europe. We launched sales of our second generation Urgent PC system in late 2006.

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

**Sales and Marketing**

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

**Corporate Information**

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

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

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**The Offering**

| | |
|---|---|
| Common stock offered: | 1,250,000 shares |
| Common stock outstanding before offering: | 13,450,140 shares as of October 5, 2007 |
| Common stock to be outstanding after offering: | 14,700,140 shares |
| Overallotment option: | 187,500 shares |
| Use of proceeds: | We expect to use the net proceeds from this offering to expand our sales and marketing organization in the United States, to conduct clinical studies to support our marketing efforts and for working capital purposes. Our management will have broad discretion in determining the specific timing and uses of the offering proceeds. |
| Risk factors: | Our business is subject to a number of risks which you should consider before investing in our company. For a discussion of the significant risks associated with our business, please read the section entitled Risk Factors beginning on page 5. |
| Trading symbol: | Our common stock is traded on the American Stock Exchange under the symbol UPI. |

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

- 2,033,100 shares of common stock subject to outstanding options, at a weighted average exercise price of $4.01 per share;
- 2,116,478 shares of common stock issuable upon the exercise of outstanding warrants, at a weighted average exercise price of $3.81 per share; and
- 529,500 shares of common stock reserved for issuance under our 2006 Stock and Incentive Plan.

Except as otherwise indicated, all information in this prospectus assumes no exercise of the underwriters overallotment option, and that 1,250,000 shares will be sold at $3.85 per share (the closing sale price of our common stock on the American Stock Exchange on November 16, 2007) in this offering. The actual public offering price per share may be higher or lower than $3.85.

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## Summary Financial Data

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

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

| | March 31, | | September 30, |
|---|---|---|---|
| | 2006 | 2007 | 2007 |
| | | | (Unaudited) |

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

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## RISK FACTORS

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

### Risks Relating to Our Company and Industry

***We continue to incur losses and may never reach profitability.***

We have incurred net losses in each of the last five fiscal years. As of September 30, 2007, we had an accumulated deficit of approximately $18.2 million primarily as a result of costs relating to the development, including seeking regulatory approvals, and commercialization of our products. We expect our operating expenses relating to sales and marketing activities, product development and clinical trials, including for FDA-mandated post-market clinical study for our Macroplastique product will continue to increase during the foreseeable future. To achieve profitability, we must generate substantially more revenue than we have in prior years. Our ability to achieve significant revenue growth will depend, in large part, on our ability to achieve widespread market acceptance for our products and successfully expand our business in the U.S., which we cannot guarantee will happen. We may never realize sufficient revenue from the sale of our products to be profitable.

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

In the U.S., we have a sales organization consisting of direct sales personnel and a network of independent sales representatives. In the United Kingdom, we have direct sales personnel. Our marketing organization supports our U.S. and U.K. sales and international distributor organizations. We anticipate continuing to expand our sales and marketing organization, as needed to support our growth. We have and will continue to incur significant additional expenses to support this organization. We may not be able to recruit, train, motivate or retain qualified sales and marketing personnel or independent sales representatives. Our ability to increase product sales in the U.S. will largely depend upon our ability to develop and maintain the sales organization. Outside of the U.S. and the U.K., we sell our products primarily through a network of independent distributors. Our ability to increase product sales in foreign markets will largely depend on our ability to develop and maintain relationships with our existing and additional distributors. We may not be able to retain distributors who are willing to commit the necessary resources to market and sell our products to the level of our expectations. Failure to expand our distribution channels or to recruit, retain and motivate qualified personnel could have a material adverse effect on our product sales and revenues.

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

Our failure to achieve sufficient market acceptance of our products in the U.S., particularly for the Urgent PC system, will limit our ability to generate revenue and be profitable. Market acceptance of our products will depend on our ability to demonstrate the safety, clinical efficacy, perceived benefits, cost-effectiveness and third party reimburseability of our products compared to products or treatment options of our competitors, and to train physicians in the proper application of our products. We cannot assure you that we will be successful in educating the marketplace about the benefits of using our products. Even if customers accept our products, this acceptance may not translate into sales if our competitors have developed similar products that our customers prefer. Furthermore, if our

products do not achieve increasing market acceptance in the U.S. and internationally, our revenues may decline or we may be unable to increase our revenues and be profitable.

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

To date, we have been dependent on sales of our products that contain our Macroplastique bulking agent. Our Macroplastique product line accounted for 51% and 67%, respectively, of total net sales during fiscal 2007 and 2006. If demand for our Macroplastique products declines, our revenues and business prospects may suffer.

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

Our future liquidity and capital requirements will depend on numerous factors including: the timing and cost involved in manufacturing scale-up and in expanding our sales, marketing and distribution capabilities in the United States markets; the cost and effectiveness of our marketing and sales efforts with respect to our existing products in international markets; the effect of competing technologies and market and regulatory developments; and the cost involved in protecting our proprietary rights. Because we have yet to achieve profitability and generate positive cash flows, we may need to raise additional financing to support our operations and planned growth activities in the future. Any equity financing could substantially dilute your equity interests in our company and any debt financing could impose significant financial and operational restrictions on us. There can be no guarantee that we will be successful, as we currently have no committed sources of, or other arrangements with respect to, additional equity or debt financing. We cannot assure you that we will obtain additional financing on acceptable terms, or at all.

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

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

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

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

- imposing fines and penalties on us;

preventing us from manufacturing or selling our products;

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bringing civil or criminal charges against us;

delaying the introduction of our new products into the market;

enforcing operating restrictions;

recalling or seizing our products; or

withdrawing or denying approvals or clearances for our products.

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

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

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

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

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

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

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

The medical device industry is litigious with respect to patents and other intellectual property rights. Companies operating in our industry routinely seek patent protection for their product designs, and many of our principal competitors have large patent portfolios. Companies in the medical device industry have used intellectual property litigation to gain a competitive advantage. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often

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uncertain. We face the risk of claims that we have infringed on third parties intellectual property rights. Our efforts to identify and avoid infringing on third parties intellectual property rights may not always be successful. Any claims of patent or other intellectual property infringement, even those without merit, could:

- be expensive and time consuming to defend;
- result in us being required to pay significant damages to third parties;
- cause us to cease making or selling products that incorporate the challenged intellectual property;
- require us to redesign, reengineer or rebrand our products, if feasible;
- require us to enter into royalty or licensing agreements in order to obtain the right to use a third party s intellectual property, which agreements may not be available on terms acceptable to us or at all;
- divert the attention of our management; and/or
- result in our customers or potential customers deferring or limiting their purchases or use of the affected products until resolution of the litigation.

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

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

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

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

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

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

product liability insurance coverage would likely be inadequate to protect us from any liabilities we may incur or we may not be able to maintain adequate product liability insurance at acceptable rates. If a product liability claim or series of claims is brought

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against us for uninsured liabilities or in excess of our insurance coverage and it is ultimately determined that we are liable, our business could suffer. Additionally, we could experience a material design or manufacturing failure in our products, a quality system failure, other safety issues or heightened regulatory scrutiny that would warrant a recall of some of our products. A recall of any of our products likely would be costly, would be uninsured and could also result in increased product liability claims. Further, while we train our physician customers on the proper usage of our products, we cannot ensure that they will implement our instructions accurately. If our products are used incorrectly by our customers, injury may result and this could give rise to product liability claims against us. Any losses that we may suffer from any liability claims, and the effect that any product liability litigation may have upon the reputation and marketability of our products, may divert management s attention from other matters and may have a negative impact on our business and our results of operations.

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

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

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

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

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

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