UROPLASTY INC
Form 424B3
September 14, 2006

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PROSPECTUS SUPPLEMENT NO. 11 Filed pursuant to Rule 424(b)(3)
(To Prospectus dated May 1, 2006) Registration No. 333-133072

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

This prospectus supplement relates to shares of our common stock that may be sold at various times by certain selling shareholders. You should read this prospectus supplement no. 11, the prior prospectus supplements and the prospectus dated May 1, 2006, which are to be delivered with this prospectus supplement. Our May 1, 2006 prospectus is a combined prospectus under Rule 429(a) of the Securities Act of 1933, as amended, with our prior prospectus dated July 29, 2005 and supplements thereto (See Registration No. 333-126737 filed with the Securities and Exchange Commission on July 20, 2005 and declared effective on July 29, 2005).

This prospectus supplement contains our Current report on Form 8-K relating to the approvable letter we received from the U.S. Food and Drug Administration for our pre-market approval application for Macroplastique Implants. This report was filed with the Securities and Exchange Commission on September 14, 2006. The attached information supplements and supersedes, in part, the information contained in the prospectus.

Our common stock is traded on the American Stock Exchange under the symbol UPI. On September 13, 2006, the closing price of our common stock on the American Stock Exchange was $2.29 per share.

This investment is speculative and involves a high degree of risk. See Risk Factors on page 6 of the prospectus 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 Supplement dated September 14, 2006

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report: September 14, 2006
UROPLASTY, INC.
(Exact name of registrant as specified in charter)

000-20989	**41-1719250**
(Commission File No.)	(IRS Employer Identification No.)

Minnesota
(State or other jurisdiction of incorporation or organization)
5420 Feltl Road
Minnetonka, Minnesota 55343
(Address of principal executive offices)
952-426-6140
(Registrant s telephone number, including area code)
Not Applicable
(Former Name and Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o Written communications pursuant to Rule 425 of the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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Item 8.01 Other Events

On September 13, 2006 we issued a press release announcing that we received an approvable letter from the U.S. Food and Dug administration (FDA) relating to our pre-market approval (PMA) application for Macroplastique Implants for the treatment of female stress urinary incontinence.

The receipt of the approvable letter follows FDA s completion of the scientific review of the safety and efficacy of Macroplastique. The FDA determined that the PMA is approvable subject to our manufacturing facilities, methods and controls being audited by the FDA and in compliance with applicable Quality System Requirements. The FDA is currently auditing our manufacturing facilities in Minneapolis, Minnesota and Eindhoven, The Netherlands.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 13, 2006 (filed herewith).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: September 14, 2006

UROPLASTY, INC.

By: /s/ Mahedi A. Jiwani
Mahedi A. Jiwani
Vice President, Chief Financial Officer
and Treasurer

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EXHIBIT 99.1

NEWS RELEASE

UROPLASTY RECEIVES FDA APPROVABLE LETTER FOR MACROPLASTIQUE

MINNEAPOLIS, MN, SEPTEMBER 13, 2006 Uroplasty, Inc. (AMEX:UPI) announced today that it has received an approvable letter from the U.S. Food and Drug Administration (FDA) relating to its pre-market approval (PMA) application for Macroplastique® Implants for the treatment of female stress urinary incontinence (SUI).

The receipt of the approvable letter follows FDA s completion of the scientific review of the safety and efficacy of Macroplastique. The FDA determined that the PMA is approvable subject to Uroplasty s manufacturing facilities, methods and controls being audited by the FDA and in compliance with applicable Quality System Requirements. The FDA is currently auditing Uroplasty s manufacturing facilities in Minneapolis, Minnesota and Eindhoven, The Netherlands.

David B. Kaysen, Uroplasty s President and CEO, commented, Macroplastique is already a market leader and a preferred treatment outside the U.S. for SUI resulting primarily from intrinsic sphincter deficiency. Since its introduction in Europe, over 60,000 people have been treated with Macroplastique and numerous clinical publications reinforce the safety and efficacy of this product. I am pleased that our development efforts, now supported by the FDA s scientific review of our safety and clinical data, are bringing us within clear sight of PMA approval and the ability to market this product in the United States. Our direct sales team is excited about adding Macroplastique to our platform of voiding dysfunction products. With this response from the FDA, we will begin preparing for the launch of Macroplastique across the U.S.

With her extensive company history and direction of these PMA clinical studies, Susan Hartjes Holman, Uroplasty s Chief Operating Officer, is extremely pleased with FDA s decision. This moves us into the final stages of FDA approval and toward our goal to bring this exceptional product to the thousands of women in this country who can benefit from Macroplastique s proven safety and performance...an effective, non-surgical treatment for a frustrating and often embarrassing condition affecting women s lifestyle, relationships and emotional well-being. Women with stress urinary incontinence may have endured their condition for years, many still having bladder control problems after previous surgical treatments. The approvable letter represents the efforts of so many of our employees worldwide. I am very proud to be associated with this product and the dedicated, capable staff at Uroplasty.

Uroplasty s patented Macroplastique is a soft tissue, injectable bulking agent for use in a minimally-invasive, out-patient procedure to treat female SUI which primarily results from intrinsic sphincter deficiency. SUI is the most common type of urinary incontinence and affects approximately 13 million Americans, 85% of whom are women. SUI is described as the sudden, accidental loss of urine during normal, everyday activities such as sneezing, coughing, laughing, straining or lifting items. Fifteen percent of the individuals with SUI suffer from a condition called intrinsic sphincter deficiency a condition in which certain muscles circling the urethra weaken and can no longer properly close to hold urine. When a physician injects Macroplastique into the tissues surrounding the urethra, the increased bulk allows the urethra to close more effectively and prevents urine from leaking.

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Mr. Kaysen continued, The anticipated FDA approval of Macroplastique s PMA marks an exciting time in Uroplasty s history. This is a significant example of Uroplasty s continued growth as a company, as well as its dedication to the treatment of urological disorders and voiding dysfunctions.

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Uroplasty, Inc., headquartered in Minnetonka, Minnesota, with wholly-owned subsidiaries in The Netherlands and the United Kingdom, is a medical device company that develops, manufactures and markets innovative, proprietary products for the treatment of voiding dysfunctions, including urinary and fecal incontinence, overactive bladder and vesicoureteral reflux.

The Urgent® PC Neuromodulation System is a proprietary, minimally invasive nerve stimulation device designed for office-based treatment of overactive bladder symptoms of urge incontinence, urinary urgency and urinary frequency. Application of neuromodulation therapy targets specific nerve tissue and disrupts the signals that lead to the symptoms of overactive bladder. Uroplasty sells the Urgent PC system in the United States, in Canada and in countries recognizing the CE mark. Outside the United States, the Urgent PC is also indicated for the treatment of fecal incontinence

The I-STOP Mid-Urethral Sling is a biocompatible, tension-free sling used to treat female stress urinary incontinence. The I-STOP sling provides a hammock-like support for the urethra to prevent urine leakage associated with activities such as coughing, laughing, lifting or jumping. Uroplasty sells the I-STOP Sling in the United Kingdom and in the United States.

Macroplastique® Implants, Uroplasty s patented soft tissue bulking agent, is used to treat both female and male urinary incontinence and to treat vesicoureteral reflux in children. When Macroplastique is injected into tissue, it stabilizes and bulks the tissue, providing the surrounding muscles with increased capability to control the flow of urine. Additionally, Uroplasty markets soft tissue bulking agents for specific indications such as PTQ Implants for the treatment of fecal incontinence, VOX® Implants for the treatment of vocal cord rehabilitation and Bioplastique® for augmentation or restoration of soft tissue defects in plastic surgery indications. Uroplasty s bulking products are sold outside the United States. We cannot assure when or if the FDA will ultimately authorize our marketing of Macroplastique in the United States, or that we can do so profitably.

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for certain forward-looking statements. This press release contains forward-looking statements, which reflect our views regarding future events and financial performance. These forward-looking statements are subject to certain risks and uncertainties, including those identified below, which could cause actual results to differ materially from historical results or those anticipated. The words aim, believe, expect, anticipate, intend, estimate and other expressions,

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which indicate future events and trends, identify forward-looking statements. Actual future results and trends may differ materially from historical results or those anticipated depending upon a variety of factors, including, but not limited to: the effect of government regulation, including when and if we receive approval for marketing products in the United States; the impact of international currency fluctuations on our cash flows and operating results; the impact of technological innovation and competition; acceptance of our products by physicians and patients, our historical reliance on a single product for most of our current sales; our ability to commercialize our recently licensed product lines; our intellectual property and the ability to prevent competitors from infringing our rights; the ability to receive third party reimbursement for our products; the results of clinical trials; our continued losses and the possible need to raise additional capital in the future; our ability to manage our international operations; our ability to hire and retain key technical and sales personnel; our dependence on key suppliers; future changes in applicable accounting rules; and volatility in our stock price.

FOR FURTHER INFORMATION: visit Uroplasty s web page at www.uroplasty.com or contact Mr. Kaysen.

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