

UROPLASTY INC
Form 8-K
July 22, 2005

**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: July 19, 2005

UROPLASTY, INC.

(Exact name of registrant as specified in charter)

000-20989

(Commission File No.)

41-1719250

(IRS Employer Identification No.)

Minnesota

(State or other jurisdiction of incorporation or organization)

2718 Summer Street NE

Minneapolis, Minnesota 55413-2820

(Address of principal executive offices)

612-378-1180

(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:

- ☐ Written communications pursuant to Rule 425 of the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events

The following forward-looking statements are subject to risks and uncertainties. We may not meet our expectations set out below for business and financial reasons. In addition to the specific risks described below, we recommend that you carefully consider the risk factors described in our other SEC filings in evaluating us.

Regulatory Matters. Uroplasty has submitted a pre-market approval application to the U.S. Food and Drug Administration relating to its Macroplastique® urethral bulking agent for the treatment of female stress urinary incontinence. On July 15, the FDA recommended additional testing of Macroplastique before considering our request for U.S. market approval. Assuming we need to conduct this additional testing, we expect to incur a delay in obtaining possible approval until late 2007.

Financial Projections. This development will also affect our previously announced sales projections for 2005 and 2006, although we have not yet quantified the impact.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits:

99.1 Press Release, dated July 19, 2005

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: July 22, 2005

UROPLASTY, INC.

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