UROPLASTY INC
Form 8-K
February 23, 2005

Table of Contents

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: February 23, 2005

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)

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:

- 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))

TABLE OF CONTENTS

Table of Contents

Item 7.01 Regulation FD Disclosure

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. We believe that we may obtain regulatory approval in late 2005. However, we cannot assure that the FDA will timely, or ever, approve our product for marketing and sale in the United States.

Uroplasty also anticipates a mid-2005 filing of a 510(k) application with the FDA covering the I-Stop® mid-urethral sling for treatment of stress urinary incontinence. We cannot assure that we will timely make this regulatory filing. Although 510(k) marketing clearance customarily requires approximately a 90-day review after submission, we cannot assure that the FDA will timely, if ever, authorize our U.S. marketing and sale of this product.

Financial Projections. Based on management s plans, we anticipate net sales of $9.0 million and $16.0 million, respectively, for calendar years 2005 and 2006. Among other assumptions, these projections assume that we consummate our proposed acquisition of CystoMedix, Inc. We are continuing our due diligence investigation of CystoMedix. We do not expect to make the acquisition by the end of our fiscal year ending March 31, 2005 and cannot assure that we will make the acquisition at all. Our projections also assume that we have obtained U.S. marketing and sales approval from the FDA for our Macroplastique and I-Stop products, which we cannot assure. Our increased revenues, if achieved, also may not necessarily yield profitable results or positively impact our stock price. In fact, by publicly announcing these projections, our stock price may decline if we do not achieve these financial milestones.

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: February 23, 2005

UROPLASTY, INC.

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