

UROPLASTY INC
Form 10QSB
February 12, 2004

Table of Contents

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

FORM 10-QSB

Quarterly Report Under section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended December 31, 2003

Commission File No. 000-20989

UROPLASTY, INC.

(Name of Small Business Issuer in its Charter)

Minnesota, U.S.A.
(State or other jurisdiction of
incorporation or organization)

41-1719250
(I.R.S. Employer
Identification No.)

**2718 Summer Street NE
Minneapolis, Minnesota 55413-2820**
(Address of principal executive offices)

(612) 378-1180
(Issuer's telephone number, including area code)

Securities registered under Section 12(g) of the Exchange Act: Common Stock, \$.01 par value (Title of class)

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES NO

The aggregate market value of the voting stock held by non-affiliates computed by reference to the price at which the stock was sold or the average bid and asked prices of such stock as of February 1, 2004 was \$16,696,512.

The number of shares outstanding of the issuer's only class of common stock on February 1, 2004 was 4,565,004.

Transitional Small Business Disclosure Format:

YES NO

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONSOLIDATED BALANCE SHEETS

CONSOLIDATED BALANCE SHEETS

CONSOLIDATED STATEMENTS OF OPERATIONS

CONSOLIDATED STATEMENTS OF CASH FLOWS

Notes to the Interim Consolidated Financial Statements

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

ITEM 3. CONTROLS AND PROCEDURES

PART II. OTHER INFORMATION

ITEM 2. CHANGES IN SECURITIES

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

SIGNATURES

Certifications of CEO & CFO - Section 302

Certifications of CEO & CFO - Section 906

Press Release

Table of Contents

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(unaudited)

| | <u>December 31, 2003</u> | <u>March 31, 2003</u> |
|-------------------------------------|-----------------------------|-----------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$2,613,903 | 3,375,981 |
| Accounts receivable, net | 1,021,959 | 969,556 |
| Inventories | 499,288 | 455,114 |
| Other | 296,677 | 188,192 |
| | <u> </u> | <u> </u> |
| Total current assets | 4,431,827 | 4,988,843 |
| Property, plant, and equipment, net | 1,075,488 | 833,234 |
| Intangible assets, net | 49,607 | 48,214 |
| | <u> </u> | <u> </u> |
| Total assets | <u>\$5,556,922</u> | <u>5,870,291</u> |

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(unaudited)

| | <u>December 31, 2003</u> | <u>March 31, 2003</u> |
|---|--------------------------|-----------------------|
| Liabilities and Shareholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 131,813 | 199,673 |
| Income tax payable | 226,365 | |
| Accrued liabilities | 317,986 | 349,937 |
| Current maturities - long-term debt | 43,350 | 37,502 |
| | <u>719,514</u> | <u>587,112</u> |
| Long-term debt - less current maturities | 502,454 | 462,787 |
| | <u>1,221,968</u> | <u>1,049,899</u> |
| Shareholders' equity: | | |
| Common stock \$.01 par value; 20,000,000 shares authorized, 4,560,337 and 4,488,971 shares issued and outstanding at December 31, 2003 and March 31, 2003, respectively | 45,603 | 44,890 |
| Additional paid-in capital | 9,066,198 | 8,457,901 |
| Accumulated deficit | (4,550,320) | (3,163,156) |
| Vendor deposit | | (112,000) |
| Deferred compensation | (168,723) | |
| Accumulated other comprehensive loss | (57,804) | (407,243) |
| | <u>4,334,954</u> | <u>4,820,392</u> |
| Total liabilities and shareholders' equity | <u>\$ 5,556,922</u> | <u>5,870,291</u> |

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|------------------------------------|-----------|-----------------------------------|-----------|
| | 2003 | 2002 | 2003 | 2002 |
| Net sales | \$ 1,447,671 | 1,264,742 | 3,982,333 | 3,862,716 |
| Cost of goods sold | 421,187 | 330,015 | 1,100,960 | 1,105,018 |
| Gross profit | 1,026,484 | 934,727 | 2,881,373 | 2,757,698 |
| Operating expenses | | | | |
| General and administrative | 510,218 | 312,003 | 1,432,263 | 884,131 |
| Research and development | 471,406 | 538,295 | 1,330,169 | 1,539,503 |
| Selling and marketing | 503,931 | 251,051 | 1,268,735 | 764,878 |
| | 1,485,555 | 1,101,349 | 4,031,167 | 3,188,512 |
| Operating loss | (459,071) | (166,622) | (1,149,794) | (430,814) |
| Other income (expense) | | | | |
| Interest income | 6,715 | 12,482 | 23,832 | 35,075 |
| Interest expense | (5,291) | (5,805) | (16,539) | (18,144) |
| Foreign currency exchange gain | 11,697 | 146,024 | 5,126 | 553,357 |
| Settlement | | | | 180,000 |
| Other | | | | (157) |
| | 13,121 | 152,701 | 12,419 | 750,131 |
| Income (loss) before income taxes | (445,950) | (13,921) | (1,137,375) | 319,317 |
| Income tax expense | 97,375 | | 249,789 | |
| Net income (loss) | \$ (543,325) | (13,921) | (1,387,164) | 319,317 |
| Basic income (loss) per common share | \$ (0.12) | (0.00) | (0.31) | 0.09 |
| Diluted income (loss) per common share | \$ (0.12) | (0.00) | (0.31) | 0.09 |
| Weighted average common shares outstanding: | | | | |
| Basic | 4,530,657 | 4,467,547 | 4,500,677 | 3,564,155 |
| Diluted | 4,530,657 | 4,467,547 | 4,500,677 | 3,587,996 |

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Nine Months Ended December 31, 2003 and 2002

(Unaudited)

| | Nine Months Ended December 31, | |
|--|-----------------------------------|------------------|
| | 2003 | 2002 |
| Cash flows from operating activities: | | |
| Net income (loss) | \$(1,387,164) | 319,317 |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operations: | | |
| Depreciation and amortization | 119,221 | 149,483 |
| Stock-based consulting expense | 304,290 | 1,508 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (52,403) | 44,905 |
| Inventories | (44,174) | 53,383 |
| Other current assets | (108,485) | (84,968) |
| Accounts payable | (39,780) | 62,320 |
| Accrued liabilities | 194,414 | (63,457) |
| Net cash provided by (used in) operating activities | <u>(1,014,081)</u> | <u>482,491</u> |
| Cash flows from investing activities: | | |
| Payments for property, plant and equipment | (63,944) | (44,757) |
| Payments for intangible assets | (18,773) | (675) |
| Net cash used in investing activities | <u>(82,717)</u> | <u>(45,432)</u> |
| Cash flows from financing activities: | | |
| Repayment of long-term debt | (29,710) | (37,674) |
| Net proceeds from issuance of stock | 49,917 | 2,265,316 |
| Net cash provided by financing activities | <u>20,207</u> | <u>2,227,642</u> |
| Effect of exchange rates on cash and cash equivalents | <u>314,513</u> | <u>(146,646)</u> |
| Net increase (decrease) in cash and cash equivalents | (762,078) | 2,518,055 |
| Cash and cash equivalents at beginning of period | 3,375,981 | 1,046,121 |
| Cash and cash equivalents at end of period | <u>\$ 2,613,903</u> | <u>3,564,176</u> |
| Supplemental disclosure of cash flow information: | | |
| Cash paid during the period for interest | \$ 17,723 | 19,503 |
| Cash paid during the period for income taxes | 38,808 | |
| Shares issued for 401(k) plan profit sharing contribution | 28,080 | 27,270 |
| Restricted shares issued for mold purchase | | 24,000 |
| Vesting of restricted shares for mold purchase | 170,000 | |

See accompanying notes to consolidated financial statements.

Table of Contents

UROPLASTY, INC. AND SUBSIDIARIES

Notes to the Interim Consolidated Financial Statements
(Unaudited)**1. Basis of Presentation**

The consolidated financial statements included in this Form 10-QSB have been prepared by Uroplasty, Inc. (Uroplasty or the Company), without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted, pursuant to such rules and regulations. The consolidated results of operations for any interim period are not necessarily indicative of results for a full year. These consolidated statements should be read in conjunction with the consolidated financial statements and related notes included in the Company's Annual Report on Form 10-KSB for the year ended March 31, 2003.

The consolidated financial statements presented herein as of December 31, 2003 and for the three and nine-months periods ended December 31, 2003 and 2002 reflect, in the opinion of management, all material adjustments consisting only of normal recurring adjustments necessary for a fair presentation of the consolidated financial position, consolidated results of operations and consolidated cash flows for the interim periods.

The Company has identified certain of its accounting policies that it considers particularly important for the portrayal of the Company's results of operations and financial position and which may require the application of a higher level of judgment by the Company's management, and as a result are subject to an inherent level of uncertainty. These are characterized as critical accounting policies and address revenue recognition, inventories, foreign currency translation and transactions, and impairment of long-lived assets, each more fully described in the Company's Annual Report on Form 10-KSB for the year ended March 31, 2003. Based upon the Company's review, management has determined that these policies remain its most critical accounting policies for the three and nine-months periods ended December 31, 2003, and has made no changes to these policies during fiscal 2004.

2. Nature of Business

The Company is currently selling its products outside of the United States and is undertaking FDA investigational clinical trials in the United States and Canada. Based on the Company's current plans, it is anticipated the Company will launch its products in the U.S. after obtaining FDA approval. Completing clinical trials and obtaining FDA approval is a costly and time-consuming process. As a result of the \$2.4 million gross proceeds of a Rights Offering completed July 2002, management believes current resources and the funds generated from sale of the Company's products outside the U.S. will be adequate to meet the Company's cash flow needs, including R&D activities, associated with existing products and markets through fiscal 2005. Ultimately, the Company will need to achieve profitability and positive cash flows from operations or obtain additional debt or equity financing to fund its operations.

3. Inventories

Inventories are stated at the lower of cost (first-in, first-out method) or market (net realizable value) and consist of the following:

| | December 31, 2003 | March 31, 2003 |
|-----------------|-------------------|----------------|
| Raw materials | \$ 107,485 | 78,910 |
| Work-in-process | 57,499 | 163,989 |
| Finished goods | 334,304 | 212,215 |
| | <u>\$ 499,288</u> | <u>455,114</u> |

Table of Contents

4. Comprehensive Income (Loss)

Comprehensive income (loss) consists of net income (loss), and the translation adjustment as follows:

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|--|------------------------------------|-----------------|-----------------------------------|----------------|
| | 2003 | 2002 | 2003 | 2002 |
| Net income (loss) | \$(543,325) | (13,921) | (1,387,164) | 319,317 |
| Items of other comprehensive income (loss): | | | | |
| Translation adjustment | 200,210 | 620 | 349,439 | (82,748) |
| Comprehensive income (loss) | <u>\$ (343,115)</u> | <u>(13,301)</u> | <u>(1,037,725)</u> | <u>236,569</u> |

5. Reconciliation of Net income (loss) and Share Amounts Used in EPS Calculation

Basic income (loss) per common share is calculated by dividing net income (loss) by the weighted-average common shares outstanding during the period. Diluted income (loss) per common share for the three and nine-months ended December 31, 2003 and 2002 was calculated using the treasury-stock method to compute the weighted average common stock outstanding assuming the conversion of dilutive potential common shares.

| | Basic Income (Loss) Per Share | Effect of Dilutive Securities | Diluted Income (Loss) Per Share |
|-----------------------------|-------------------------------------|-------------------------------------|---------------------------------------|
| For the three months ended: | | | |
| December 31, 2003 | | | |
| Net loss | \$ (543,325) | | (543,325) |
| Shares | 4,530,657 | | 4,530,657 |
| Per share amount | <u>\$ (0.12)</u> | | <u>(0.12)</u> |
| For the three months ended: | | | |
| December 31, 2002 | | | |
| Net loss | \$ (13,921) | | (13,921) |
| Shares | 4,467,547 | | 4,467,547 |
| Per share amount | <u>\$ (0.00)</u> | | <u>(0.00)</u> |
| For the nine months ended: | | | |
| December 31, 2003 | | | |
| Net loss | \$(1,387,164) | | (1,387,164) |
| Shares | 4,500,677 | | 4,500,677 |
| Per share amount | <u>\$ (0.31)</u> | | <u>(0.31)</u> |
| For the nine months ended: | | | |
| December 31, 2002 | | | |
| Net income | \$ 319,317 | | 319,317 |

Table of Contents

| | Basic Income (Loss) Per Share | Effect of Dilutive Securities | Diluted Income (Loss) Per Share |
|------------------|--|--|--|
| Shares | 3,564,155 | 23,841 | 3,587,996 |
| Per share amount | \$ 0.09 | | 0.09 |

The following options and warrants outstanding at December 31, 2003 and 2002 to purchase shares of common stock were excluded from diluted loss per share, because of the anti-dilutive effect:

| | Number of Options/Warrants | Range of exercise prices |
|-----------------------------|---------------------------------------|-------------------------------------|
| For the three months ended: | | |
| December 31, 2003 | 1,752,264 | \$0.90 to \$10.50 |
| December 31, 2002 | 1,705,123 | \$0.90 to \$10.50 |
| For the nine months ended: | | |
| December 31, 2003 | 1,752,264 | \$0.90 to \$10.50 |
| December 31, 2002 | 1,261,623 | \$1.50 to \$10.50 |

6. Shareholders Equity

The Company applies the intrinsic-value method to account for employee stock-based compensation. As such, compensation expense, if any, is recorded on the date of grant if the current market price of the underlying stock exceeds the exercise price.

The Company accounts for stock-based instruments granted to non-employees under the fair value method of SFAS No. 123 and Emerging Issues Task Force (EITF) 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*. Under SFAS No. 123, options are recorded at their fair value on the measurement date, which is typically the vesting date.

Consulting Agreements

On April 1, 2003, the Company executed a consulting agreement with C.C.R.I. Corporation (CCRI) to provide investor relations and development services. The Company pays the Consultant a monthly fee of \$4,000 plus expenses. CCRI received 35,000 shares of fully vested restricted common stock, and vested warrants to purchase 50,000 shares of common stock at an exercise price of \$3.00 per share, and received vested warrants to purchase 50,000 shares of common stock at an exercise price of \$5.00 per share on November 2, 2003. The Company recorded the fair value of the common stock and the warrants aggregating \$212,974, as of April 1, 2003, as deferred compensation in shareholders' equity. The balance is amortized over the 1-year service period. Also, the Company recorded the fair value of the additional warrants to acquire 50,000 of common stock aggregating \$144,200, as of November 2, 2003, as deferred compensation in shareholders' equity. This balance is amortized over the remaining 5 months of the 1-year service period. Stock-based compensation expense for CCRI agreement for the three and nine-months ended December 31, 2003 aggregated \$110,924 and \$217,410, respectively.

On April 1, 2003, the Company executed a consulting agreement with Executive Advisory Group (EAG) to perform services for and on behalf of the Company. Mr. Sam B. Humphries, a Director of the Company, is President of EAG. The Company pays EAG a monthly fee of \$6,000 plus expenses. EAG also received stock options to purchase 50,000 shares of common stock, exercisable at \$2.80 per share. The Company recorded the fair value of the stock options aggregating \$115,839, as of April 1, 2003, as a deferred compensation in shareholders' equity. The balance is amortized over the 1-year service period. Stock-based compensation expense for the EAG agreement for the three and nine-months ended December 31, 2003 aggregated \$28,959 and \$86,880, respectively.

Table of Contents

The options and warrants issued to EAG and CCRI to acquire an aggregate of 150,000 shares of common stock were fully vested upon issuance. The fair value of these instruments was determined using the Black-Scholes options pricing model with the following variables:

| | April 1, 2003 | November 2, 2003 |
|-------------------------|---------------|------------------|
| Expected dividend yield | 0.00% | 0.00% |
| Risk-free interest rate | 2.93% | 3.29% |
| Expected volatility | 118% | 113% |
| Expected life, in years | 5.00 | 5.00 |

Stock Option Grant

On April 15, 2003, the Company granted 30,000 options to its Director Sam B. Humphries, for his services as a member of the board of directors. These options vest over a period of five years. All vesting of these options would accelerate when the Company receives written FDA market approval or in case a change in control should occur.

Vendor Deposit

In September 2001, the Company executed an agreement with a vendor to manufacture a mold for one of the Company's products. As consideration, the Company issued to the vendor 20,000 shares of its common stock in September 2001. The Company amended the agreement in September 2002 and issued an additional 20,000 shares of common stock to be held in escrow until completion of the mold. On November 3, 2003, the Company has accepted the mold and recorded the fair value of the vested common stock aggregating \$170,000 as an addition to property, plant and equipment.

7. Stock Option Plans

Had the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS 123, Accounting for Stock-Based Compensation, the Company's net income (loss) would have decreased (increased) to the pro forma amounts shown below:

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|------------------------------------|-----------|-----------------------------------|-----------|
| | 2003 | 2002 | 2003 | 2002 |
| Net income (loss) - As reported | \$(543,325) | (13,921) | (1,387,164) | 319,317 |
| Add: Total stock-based employee compensation expense determined under intrinsic value based method for all awards | | | | |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards | (37,254) | (100,283) | (111,761) | (270,169) |
| Net income (loss) - Pro forma | \$(580,579) | (114,204) | (1,498,925) | 49,148 |

Table of Contents

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|------------------------------------|--------|-----------------------------------|------|
| | 2003 | 2002 | 2003 | 2002 |
| Net income (loss) per common share As reported: | | | | |
| Basic | \$ (0.12) | (0.00) | (0.31) | 0.09 |
| Diluted | \$ (0.12) | (0.00) | (0.31) | 0.09 |
| Net income (loss) per common share Pro forma: | | | | |
| Basic | \$ (0.13) | (0.03) | (0.33) | 0.01 |
| Diluted | \$ (0.13) | (0.03) | (0.33) | 0.01 |

8. Foreign Currency Gains (Losses)

For the three-month periods ended December 31, 2003 and 2002, the Company recognized foreign currency gains of \$11,697 and \$146,024, respectively. For the nine-month periods ended December 31, 2003 and 2002, the Company recognized foreign currency gains of \$5,126 and \$553,357, respectively. At December 31, 2003 and 2002, the Company had \$0.3 million and \$2.5 million of dollar denominated intercompany debt at its Dutch subsidiaries. In January 2003, the Company recapitalized one of the Dutch subsidiaries with an investment of 1.5 million euros (\$1.6 million). The proceeds from the investment were used to reduce the dollar denominated intercompany debt at the Dutch subsidiary. Furthermore, the Dutch subsidiaries were profitable and the generated cash flows were used to pay off the intercompany debt. These intercompany balances are revolving in nature and are not deemed to be long-term balances.

9. Income Tax Expense

During the quarter ended December 31, 2003, the Company's Dutch subsidiaries recorded income tax expense of \$97,375 as they have fully utilized their net operating loss carryforwards. During the nine months ended December 31, 2003, the Company's Dutch subsidiaries recorded income tax expense of \$249,789. As of December 31, 2003 \$38,808 income tax has been paid and the remaining balance is included under current liabilities. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions.

10. Business Segment Information

The Company sells Macroplastique and the related ancillary products for use in augmenting soft tissues for the purpose of treating urinary incontinence and vesicoureteral reflux. At this time, sales are only made outside the United States because the Company has not yet made submissions to the FDA for regulatory approval to market its products in the United States. The Company's current objectives are to focus on sales and marketing activities designed to increase market penetration and sales of Macroplastique for SUI, VUR, and of PTQ Implants in countries outside the U.S., and to efficiently and effectively execute the Macroplastique human clinical study for treatment of female SUI within the U.S. The Company also sells injectable implant products outside the United States for soft-tissue augmentation for specific indications in otolaryngology and plastic surgery applications under the name Bioplastique in limited markets. In addition, the Company sells specialized wound care products in The Netherlands and United Kingdom as a distributor. The Macroplastique product line accounts for 84% to 87% of total net sales during the periods presented.

Based upon the above, the Company has identified one reportable operating segment consisting of medical products primarily for the urology market.

Information regarding operations in different geographies for the three and nine-months ended December 31, 2003 and 2002 is as follows:

Table of Contents

| | United States | The Netherlands | United Kingdom | Adjustments and eliminations | Consolidated |
|--|------------------|--------------------|-------------------|------------------------------------|--------------|
| Fiscal 2004 | | | | | |
| Sales to customers, three-months ended December 31, 2003 | \$ | 1,317,858 | 391,180 | (261,367) | 1,447,671 |
| Sales to customers, nine-months ended December 31, 2003 | \$ | 3,586,988 | 1,085,354 | (690,009) | 3,982,333 |
| Income tax expense, three-months ended December 31, 2003 | \$ | 97,375 | | | 97,375 |
| Income tax expense, nine-months ended December 31, 2003 | \$ | 249,789 | | | 249,789 |
| Net income (loss), three-months ended December 31, 2003 | \$ (500,277) | 180,012 | (117,627) | (105,433) | (543,325) |
| Net income (loss), nine-months ended December 31, 2003 | \$ (1,308,535) | 482,179 | (334,365) | (226,443) | (1,387,164) |
| Long-lived assets At December 31, 2003 | \$ 267,589 | 786,180 | 21,719 | | 1,075,488 |
| Fiscal 2003 | | | | | |
| Sales to customers, three-months ended December 31, 2002 | \$ | 1,092,721 | 366,274 | (194,253) | 1,264,742 |
| Sales to customers, nine-months ended December 31, 2002 | \$ | 3,366,401 | 1,297,844 | (801,529) | 3,862,716 |
| Income tax expense, three-months ended December 31, 2002 | \$ | | | | |
| Income tax expense, nine-months ended December 31, 2002 | \$ | | | | |
| Net income (loss), three-months ended December 31, 2002 | \$ (563,990) | 457,623 | (53,047) | 145,493 | (13,921) |
| Net income (loss), nine-months ended December 31, 2002 | \$ (1,071,362) | 1,246,002 | (18,059) | 162,736 | 319,317 |
| Long-lived assets At December 31, 2002 | \$ 103,945 | 698,508 | 26,977 | | 829,430 |

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

This Report on Form 10-QSB should be read in conjunction with the Annual Report on Form 10-KSB for the year ended March 31, 2003.

Forward-looking Statements

The Registrant may from time to time make written or oral forward-looking statements, including statements contained in this filing by the Company with the Securities and Exchange Commission and in its reports to stockholders, as well as elsewhere. Forward-looking statements are statements such as those contained in projections, plans, objectives, estimates, statements of future economic performance, and assumptions related to any of the foregoing, and may be identified by the use of forward-looking terminology, such as may, expect, anticipate, estimate, go

Edgar Filing: UROPLASTY INC - Form 10QSB

continue , or other comparable terminology. By their very nature, forward-looking statements are subject to known and

Table of Contents

unknown risks and uncertainties relating to the Company's future performance that may cause the actual results, performance, or achievements of the Company, or industry results, to differ materially from those expressed or implied in any such forward-looking statements. Any such statement is qualified by reference to the following cautionary statements.

The Registrant's business operates in highly competitive markets and is subject to changes in general economic conditions, competition, customer and market preferences, government regulation, the impact of tax regulation, foreign exchange rate fluctuations, the degree of market acceptance of products, the uncertainties of potential litigation, as well as other risks and uncertainties detailed elsewhere herein and from time to time in the Registrant's Securities and Exchange Commission filings.

In this filing, the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" contains forward-looking statements. Various factors and risks (not all of which are identifiable at this time) could cause the Company's results, performance, or achievements to differ materially from that contained in the Company's forward-looking statements, and investors are cautioned that any forward-looking statement contained herein or elsewhere is qualified by and subject to the warnings and cautionary statements contained above and in the Company's other filings with the Securities and Exchange Commission.

The Company does not undertake and assumes no obligation to update any forward-looking statement that may be made from time to time by or on behalf of the Company.

Overview

Uroplasty, Inc. develops, manufactures, and/or markets medical products in certain segments of the urology, gynecology, urogynecology, colon and rectal, wound care, otolaryngology and plastic surgery markets. Products sold by the Company are subject to regulation by the U.S. FDA and/or various regulating agencies in countries outside the U.S. Existing sales have been, and future sales growth is expected to be, derived from Macroplastique and related ancillary products designed for use by urologists, gynecologists, and uro-gynecologists for the treatment of stress urinary incontinence (SUI) and for the treatment of vesicoureteral reflux (VUR), a condition in which urine flows backward from the bladder to the kidney. Macroplastique is comprised of soft, irregularly textured, vulcanized, medical grade silicone elastomer implants suspended in a biocompatible carrier solution. When injected via a minimally invasive procedure in the soft tissue of the mid-urethra and bladder neck (in the case of SUI), and at the ureteral orifice (in the case of vesicoureteral reflux), the implants act as a bulking material to restore urinary continence or to eliminate reflux of urine from the bladder to the kidneys.

In addition to the urological applications, the Company's implantable tissue bulking material is also marketed by the Company outside the U.S. for reconstructive and cosmetic plastic surgery applications under the trade name Bioplastique Implants; fecal incontinence applications under the trade name PTP Implants; and vocal cord rehabilitation under the trade name VOX Implants. In The Netherlands and the United Kingdom, the Company's direct sales force distributes certain wound care products on behalf of another company in accordance with an executed Distributor Agreement. Under the terms of the Distributor Agreement, the Company is not obligated to purchase any minimum level of wound care products.

The Company's products are currently sold by direct sales forces in the United Kingdom and The Netherlands, and by a network of distributors in numerous countries outside the U.S., including Western Europe, Australia, Canada and Central and South America. The Company is currently conducting a multi-center human clinical trial with its urethral bulking agent, Macroplastique, pursuant to an FDA IDE as a minimally invasive, office-based procedure for treating female SUI. This study is required as part of a Premarket Approval Submission to the FDA for marketing within the United States.

The Company's objectives are to focus on sales and marketing activities designed to increase market penetration and sales of Macroplastique for SUI, VUR, and of PTP Implants for fecal incontinence applications in countries outside the U.S., and to efficiently and effectively execute the Macroplastique clinical study for treatment of female SUI within the U.S.

Critical Accounting Policies

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America, which require the Company to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing these financial statements, management has made its best estimates and judgments of certain amounts, giving due consideration to materiality. The Company believes that of its significant accounting policies, the following are particularly important to the portrayal of the Company's

Table of Contents

results of operations and financial position and may require the application of a higher level of judgment by the Company's management, and as a result are subject to an inherent degree of uncertainty.

Revenue Recognition and Accounts Receivable. The level of the Company's revenue during any period is not necessarily indicative of its distributors' sales to end-user customers during that period, which are estimated not to be substantially different than the Company's sales to those distributors in each of the last two years. The Company's future revenue growth may be impacted by its distributors' level of inventories of the Company's products, their sales to end-user customers and their internal product requirements.

Inventories. Slow moving and obsolete inventories are valued at the lower of cost or market based upon current and expected future product sales and the expected impact of product transitions or modifications. In addition, the lack of sales demand may cause our finished goods inventory to pass its use-by date which is generally two years. The Company manufacturing production from quarter to quarter fluctuates materially due to changes in product demand. Changes in production significantly impact manufacturing variances.

Foreign Currency Translation/Transactions. Foreign currency transaction gains and losses are recognized currently in the statement of operations, including unrealized gains and losses on short-term inter-company obligations using period-end exchange rates, resulting in an increase in the volatility of the Company's Statements of Operations. Unrealized gains and losses on long-term inter-company obligations are recognized within accumulated other comprehensive loss, a separate component of shareholders' equity.

Impairment of Long-Lived Assets. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset, which is subject to considerable judgment.

Set forth below is management's discussion and analysis of the financial condition and results of operations for the three and nine-months periods ended December 31, 2003 and 2002.

Results of Operations

Net Sales: In the third quarter ended December 31, 2003, net sales of all products were \$1,447,671, representing a \$182,929 or 14% increase when compared to net sales of \$1,264,742 for the third quarter ended December 31, 2002. During the nine months ended December 31, 2003, net sales of all products were \$3,982,333, representing a \$119,617 or 3% increase when compared to net sales of \$3,862,716 during the nine months ended December 31, 2002. The sales increase is the result of favorable fluctuations in foreign currency exchange rates between the U.S. Dollar (the functional reporting currency) and the Euro and the British Pound (currencies of the Company's subsidiaries). Excluding the fluctuations in foreign currency exchange rates, there was a sales decrease of approximately 1% for the three months ended December 31, 2003 and approximately 11% for the nine months ended. Management believes the decrease in sales is related to increased competition and healthcare reform in many European countries with procedures being limited or rationed through reimbursement systems designed to decrease overall costs to the various national healthcare systems. Management believes sales will increase going forward with targeted marketing programs. The Macroplastic product line accounts for 84% to 87% of total net sales during the periods presented.

Gross Profit: Gross profit was \$1,026,484 and \$934,727 for the quarter ended December 31, 2003 and 2002, respectively, or 71% and 74% of net sales. Gross profit was \$2,881,373 and \$2,757,698 for the nine months ended December 31, 2003 and 2002, respectively, or 72% and 71% of net sales. Gross profit in any one period is highly variable depending on unit sales and utilization of manufacturing capacity. Historically, the gross margin percentage has moved between approximately 70-80% of net sales.

General and Administrative Expense: General and administrative (G&A) expenses increased from \$312,003 during the third quarter of fiscal 2003 to \$510,218 during the third quarter of fiscal 2004 and increased from \$884,131 during the nine months ended December 31, 2002 to \$1,432,263 during the nine months ended December 31, 2003. Increased foreign retirement costs, consulting, legal, and shareholder expenses, combined with general price increases and fluctuations in foreign currency exchange rates caused the increase in G&A expenses. The consulting fees and shareholder expenses relate to the consulting agreements with the Executive Advisory Group (EAG) to perform services for and on behalf of the Company and the consulting agreement with C.C.R.I. Corporation to provide investor relations and development services. The two agreements accounted for \$169,883 and \$402,290, respectively, of the increased expense for the three and nine months ended December 31, 2003.

Table of Contents

Research and Development Expense: Research and development (R&D) expenses decreased \$66,889, or 12%, from \$538,295 during the third quarter of fiscal 2003 to \$471,406 during the third quarter of fiscal 2004 and decreased 14% from \$1,539,503 during the nine months ended December 31, 2002 to \$1,330,169 during the nine months ended December 31, 2003. The decrease in R&D expense resulted from a decrease in clinical costs due to the February 2003 completion of the patient enrollment phase in the Company's multi-center IDE clinical trial.

Selling and Marketing Expenses: Selling and marketing (S&M) costs increased 101% from \$251,051 during the third quarter of fiscal 2003 to \$503,931 during the third quarter of fiscal 2004 and increased 66% from \$764,878 during the nine months ended December 31, 2002 to \$1,268,735 during the nine months ended December 31, 2003. The increase resulted from recruitment fees, staffing, and dismissal payments, travel costs and costs relating to trade-shows, conventions and congresses, marketing materials, general price increases, and fluctuations in foreign currency exchange rates. In October and December, changes were made in sales management resulting in termination expenses and payments in the third quarter of fiscal 2004 of \$105,000.

Other Income (Expense): Other income (expense) includes interest income, interest expense, foreign currency exchange gains and losses, settlement income and other non-operating costs when incurred. The Company's financial results are subject to material fluctuations based on changes in currency exchange rates. Other income was \$13,121 and \$152,701 for the third quarter ended December 31, 2003 and 2002, respectively, and \$12,419 and \$750,131 for the nine months ended December 31, 2003 and 2002, respectively. The majority of the differences between periods were due to foreign currency exchange gains and losses and the settlement proceeds from the litigation. Exchange gains and losses are recognized primarily as a result of fluctuations in currency rates between the U.S. Dollar (the functional reporting currency) and the Euro and British Pound (currencies of the Company's subsidiaries), as well as their effect on the dollar denominated intercompany obligations between the Company and its foreign subsidiaries. At December 31, 2003 and 2002, the Company had \$0.3 million and \$2.5 million dollar denominated intercompany debt at its foreign Dutch subsidiary. These intercompany balances are revolving in nature and are not deemed to be long-term balances. The Company recognized foreign currency gains of \$11,697 and \$146,024 for the third quarter ended December 31, 2003 and 2002, respectively, and \$5,126 and \$553,357 for the nine months ended December 31, 2003 and 2002, respectively. The currency gains are primarily the result of a weakened U.S. Dollar compared to the Euro. In January 2003, the Company recapitalized one of the Dutch subsidiaries with an investment of 1.5 million Euros (\$1.6 million). The Company used proceeds from the investment to reduce the dollar denominated intercompany debt at the Dutch subsidiary, resulting in an adjusted balance at December 31, 2002 of \$0.9 million of intercompany debt at the Dutch subsidiary subject for foreign currency transaction accounting. This resulted in less volatility for changes in currency exchange rates in the Company's statement of operations.

Income Tax Expense: During the quarter ended December 31, 2003, the Company's Dutch subsidiaries recorded income tax expense of \$97,375 as they have fully utilized their net operating loss carryforwards. During the nine-months ended December 31, 2003, the Company's Dutch subsidiaries recorded income tax expense of \$249,789. As of December 31, 2003 \$38,808 income tax has been paid, the remaining part has been accrued and therefore included under current liabilities. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. Management expects continued profits for its Dutch subsidiaries and therefore continued income tax expenses. The Dutch income tax rate is 29% for euro 22,689 of profit and 34.5% for the amount above euro 22,689

Liquidity and Capital Resources

As of December 31, 2003, the Company's cash and cash equivalent balances totaled \$2,613,903.

At December 31, 2003, the Company had working capital of approximately \$3.7 million. During the nine months ended December 31, 2003, \$1,014,081 of cash was used in operating activities, compared to \$482,491 of cash provided by operating activities in the prior-year period. The usage of cash was primarily attributable to the net loss incurred of \$1,387,164, compared to a profit of \$319,317 in the prior year period. Accounts receivable increased by \$52,403, compared to a decrease of \$44,905 for the prior-year period, due to the timing of payment by our customers. Other current assets increased by \$108,485, compared to an increase of \$84,968 for the prior-year period, due to prepaid retirement premiums, royalties and insurance. Accounts payable and accrued expenses fluctuated due to the timing of payments and fluctuations in foreign currency exchange rates. The Company recorded \$304,290 of non-cash stock-based compensation expense during the nine-months ended December 31, 2003, compared to \$1,508 for the prior-year period. This increase was due to the stock-based investor relations and other consulting agreements the Company consummated on April 1, 2003 with C.C.R. Corporation and Executive Advisory Group. Net cash used in investing activities for the nine months ended December 31, 2003 is \$82,717, compared to net cash used of \$45,432 for the prior-year

Table of Contents

period. The increase was due to computer hardware and software expenditures and expenditures for obtaining patent rights. Net cash provided by financing activities for the nine months ended December 31, 2003 is \$20,207, compared to net cash provided by financing activities of \$2,227,642. This results from repayment of long-term debt and net proceeds from issuance of stock. In July 2002, the Company completed its rights offering to its shareholders.

The Company currently has no financing arrangements in place with any bank for general working capital needs, and no material unused sources of liquidity other than the cash, equipment leasing arrangements, and its accounts receivable and inventory balances at December 31, 2003 of \$1,021,959 and \$499,288, respectively. For fiscal 2004, management does not anticipate any material capital expenditures.

The Company's financial condition and results of operations could be materially affected by fluctuations in foreign currency exchange rates and weak economic conditions in foreign markets where the Company's products are distributed. The effects of these conditions could include reduced unit sales and reduced sales in dollars when converted from foreign currency amounts and material gains and losses on transactions denominated in foreign currencies. Furthermore, because the Company's U.S. operations are funded by sales denominated in foreign currency, strengthening of the U.S. dollar against the Euro, and/or the British Pound could have an adverse effect on the Company's cash flow and results of operations.

Management expects continued high costs associated with the conduct of the U.S. human clinical study for Macroplastique pursuant to the FDA approved IDE, the subsequent U.S. Premarket Approval process, and pre-commercialization and market launch costs in the U.S. relating to Macroplastique for female SUI.

Management believes that current resources and the funds generated from sale of the Company's products outside the U.S. will be adequate to meet the Company's cash flow needs, including R&D activities associated with existing products and markets through fiscal 2005. Ultimately, the Company will need to achieve profitability and positive cash flows from operations or obtain additional debt or equity financing to fund its operations.

ITEM 3. CONTROLS AND PROCEDURES.

Disclosure Controls and Procedures. Within the 90 days prior to the date of this report, Daniel G. Holman, our President, Chief Executive Officer, Chief Financial Officer and Arie J. Koole, our Controller, Principal Accounting Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15b under the Securities Exchange Act of 1934. Based on their review of our disclosure controls and procedures, such officers have concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to us that is required to be included in our periodic SEC filings.

Internal Controls and Procedures. There were no significant changes in internal controls or in other factors that could significantly affect these controls subsequent to the date of their evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Table of Contents

PART II. OTHER INFORMATION

Except as indicated below, none of the items contained in PART II of Form 10-QSB are applicable to the Company for the three months ended December 31, 2003.

ITEM 2. CHANGES IN SECURITIES

(c) Recent Sales of Unregistered Securities

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits

31 Certifications by the Chief Executive Officer/Chief Financial Officer and the Controller pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

32 Certifications by the Chief Executive Officer/Chief Financial Officer and the Controller pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (this Exhibit is furnished pursuant to SEC rules, but is deemed not filed)

99.1 Press release dated February 12, 2004

(b) Reports on Form 8-K

None

Table of Contents

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

UROPLASTY, INC.

Date: February 12, 2004

by: /s/ DANIEL G. HOLMAN _____

Daniel G. Holman
President, Chief Executive Officer,
Chief Financial Officer and Director (Principal
Executive and Financial Officer)

Date: February 12, 2004

by: /s/ ARIE J. KOOLE _____

Arie J. Koole
Controller (Principal Accounting Officer)