UROPLASTY INC
Form 10QSB
February 11, 2005

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**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, 2004**

**Commission File No. 000-20989**

**UROPLASTY, INC.**

(Name of Small Business Issuer in its Charter)

| **Minnesota, U.S.A.** | **41-1719250** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (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 þ NO o

The number of shares outstanding of the issuer s only class of common stock on February 1, 2005 was 4,691,497.

Transitional Small Business Disclosure Format:

YES o NO þ

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PART I. FINANCIAL INFORMATION

**ITEM 1. FINANCIAL STATEMENTS**

UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

| | December 31, 2004 (unaudited) | March 31, 2004) |
|---|---|---|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,885,757 | $ 2,697,670 |
| Accounts receivable, net | 1,180,398 | 1,065,176 |
| Inventories | 573,255 | 519,130 |
| Other | 199,074 | 235,078 |
| Total current assets | 3,838,484 | 4,517,054 |
| Property, plant, and equipment, net | 1,099,052 | 1,071,116 |
| Intangible assets, net | 42,265 | 51,495 |
| Deferred tax assets | 155,793 | 123,893 |
| Total assets | $ 5,135,594 | $ 5,763,558 |

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

| | December 31, 2004 (unaudited) | March 31, 2004 |
|---|---|---|
| Liabilities and Shareholders Equity | | |
| Current liabilities: | | |
| Current maturities long-term debt | $ 46,560 | $ 42,301 |
| Accounts payable | 231,049 | 225,315 |
| Accrued liabilities | 372,823 | 475,957 |
| Income tax payable | 154,217 | 101,562 |
| Total current liabilities | 804,649 | 845,135 |
| Long-term debt less current maturities | 493,109 | 479,720 |
| Accrued pension liability | 373,720 | 334,470 |
| Total liabilities | 1,671,478 | 1,659,325 |
| Shareholders equity: | | |
| Common stock $.01 par value; 20,000,000 shares authorized, 4,691,497 and 4,584,802 shares issued and outstanding at December 31, 2004 and March 31, 2004, respectively | 46,915 | 45,848 |
| Additional paid-in capital | 9,334,325 | 9,130,580 |
| Accumulated deficit | (5,876,598) | (4,756,622) |
| Accumulated other comprehensive loss | (40,526) | (315,573) |
| Total shareholders equity | 3,464,116 | 4,104,233 |
| Total liabilities and shareholders equity | $ 5,135,594 | $ 5,763,558 |

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| Net sales | $ 1,609,692 | $ 1,447,671 | $ 5,012,912 | $ 3,982,333 |
| Cost of goods sold | 383,573 | 404,130 | 1,317,303 | 1,107,105 |
| Gross profit | 1,226,119 | 1,043,541 | 3,695,609 | 2,875,228 |
| Operating expenses | | | | |
| General and administrative | 504,390 | 493,905 | 1,403,762 | 1,450,447 |
| Research and development | 558,719 | 454,349 | 1,724,488 | 1,336,313 |
| Selling and marketing | 416,886 | 487,619 | 1,535,642 | 1,286,922 |
| | 1,479,995 | 1,435,873 | 4,663,892 | 4,073,682 |
| Operating loss | (253,876) | (392,332) | (968,283) | (1,198,454) |
| Other income (expense) | | | | |
| Interest income | 8,015 | 6,715 | 23,093 | 23,832 |
| Interest expense | (5,361) | (5,291) | (15,682) | (16,539) |
| Foreign currency exchange loss | (6,478) | 11,697 | (20,564) | 5,126 |
| | (3,824) | 13,121 | (13,153) | 12,419 |
| Loss before income taxes | (257,700) | (379,211) | (981,436) | (1,186,035) |
| Income tax expense | 86,311 | 120,914 | 138,540 | 241,309 |
| Net loss | $ (344,011) | $ (500,125) | $ (1,119,976) | $ (1,427,344) |
| Basic and diluted loss per common share | $ (0.07) | $ (0.11) | $ (0.24) | $ (0.32) |
| Weighted average common shares outstanding: | | | | |
| Basic and diluted | 4,670,522 | 4,530,657 | 4,638,628 | 4,500,677 |

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
Nine Months Ended December 31, 2004 and 2003
(Unaudited)

| | Nine Months Ended December 31, | |
|---|---|---|
| | **2004** | **2003** |
| Cash flows from operating activities: | | |
| Net loss | $ (1,119,976) | $ (1,427,344) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 122,869 | 118,706 |
| Loss on disposal of assets | 3,987 | |
| Stock-based consulting expense | | 304,290 |
| Deferred tax assets | (19,053) | (15,164) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (18,397) | 84,563 |
| Inventories | 23,603 | 88,411 |
| Other current assets | 43,963 | 7,710 |
| Accounts payable | (3,734) | (49,119) |
| Accrued liabilities | (76,513) | 118,320 |
| Accrued pension liability | 9,821 | 11,106 |
| Additional pension liability | (996) | (2,222) |
| Net cash used in operating activities | (1,034,426) | (760,743) |
| Cash flows from investing activities: | | |
| Payments for property, plant and equipment | (61,304) | (63,669) |
| Payments for intangible assets | (7,277) | (18,773) |
| Net cash used in investing activities | (68,581) | (82,442) |
| Cash flows from financing activities: | | |
| Repayment of long-term debt | (32,032) | (29,383) |
| Net proceeds from issuance of stock | 204,812 | 49,917 |
| Net cash provided by financing activities | 172,780 | 20,534 |
| Effect of exchange rates on cash and cash equivalents | 118,314 | 60,573 |
| Net decrease in cash and cash equivalents | (811,913) | (762,078) |

| | | |
|---|---|---|
| Cash and cash equivalents at beginning of period | 2,697,670 | 3,375,981 |
| Cash and cash equivalents at end of period | $ 1,885,757 | $ 2,613,903 |
| Supplemental disclosure of cash flow information: | | |
| Cash paid during the period for interest | $ 16,583 | $ 17,723 |
| Cash paid during the period for income taxes | 113,136 | 38,808 |
| Shares issued for 401(k) plan profit sharing contribution | | 28,080 |
| Vesting of restricted shares for mold purchase | | 170,000 |

See accompanying notes to the condensed interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES

Notes to the Condensed Interim Consolidated Financial Statements
(Unaudited)

**1. Basis of Presentation**

We have prepared our condensed consolidated financial statements included in this Form 10-QSB, 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 condensed consolidated statements should be read in conjunction with the consolidated financial statements and related notes included in our Annual Report on Form 10-KSB for the year ended March 31, 2004.

The condensed consolidated financial statements presented herein as of December 31, 2004 and for the three and nine-months periods ended December 31, 2004 and 2003 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, results of operations and cash flows for the interim periods.

We have identified certain accounting policies that we consider particularly important for the portrayal of our 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 of which is more fully described in our Annual Report on Form 10-KSB for the year ended March 31, 2004. Based upon our review, we have determined that these policies remain our most critical accounting policies for the three and nine-months periods ended December 31, 2004, and have made no changes to these policies during fiscal 2005.

**2. Nature of Business and Corporate Liquidity**

We currently sell our products outside of the United States and are pursuing regulatory approvals to market our products in the United States. We anticipate increasing our sales and marketing activities in the U.S. once we obtain such approvals. The FDA approval process can be costly, lengthy and uncertain. As a result of the $2.4 million gross proceeds of a Rights Offering completed July 2002, we believe that current resources and the funds generated from sale of our products outside the U.S. will be adequate to meet our cash flow needs, including regulatory activities associated with existing products, through at least the first quarter of fiscal 2006. Ultimately, we will need to achieve profitability and positive cash flows from operations and to raise additional debt or equity financing to fund our operations and grow our business.

**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, 2004 | March 31, 2004 |
|---|---|---|
| Raw materials | $ 190,110 | $ 138,920 |

| | | |
|---|---|---|
| Work-in-process | 93,913 | 110,511 |
| Finished goods | 289,232 | 269,699 |
| | $ 573,255 | $ 519,130 |

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**4. Comprehensive Loss**

Comprehensive loss consists of net loss, and the translation adjustments as follows:

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | **2004** | **2003** | **2004** | **2003** |
| Net loss | $ (344,011) | $ (500,125) | $ (1,119,976) | $ (1,427,344) |
| Items of other comprehensive income (loss): | | | | |
| Translation adjustment | 253,170 | 183,201 | 285,164 | 320,590 |
| Additional pension liability | (9,129) | (4,294) | (10,117) | (7,709) |
| Comprehensive loss | $ (99,970) | $ (321,218) | $ (844,929) | $ (1,114,463) |

**5. Reconciliation of Net Loss and Per Share Amounts Used in EPS Calculation**

Basic and diluted loss per common share is calculated by dividing net loss by the weighted-average common shares outstanding during the period.

| | **Basic and Diluted Loss Per Share** |
|---|---|
| For the three months ended: | |
| December 31, 2004 | |
| Net loss | $ (344,011) |
| Weighted average shares | 4,670,522 |
| Per share amount | $ (0.07) |
| For the three months ended: | |
| December 31, 2003 | |
| Net loss | $ (500,125) |
| Weighted average shares | 4,530,657 |
| Per share amount | $ (0.11) |
| For the nine months ended: | |
| December 31, 2004 | |
| Net loss | $ (1,119,976) |
| Weighted average shares | 4,638,628 |
| Per share amount | $ (0.24) |

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| | Basic and Diluted Loss Per Share |
|---|---|
| For the nine months ended: | |
| December 31, 2003 | |
| Net loss | $ (1,427,344) |
| Weighted average shares | 4,500,677 |
| Per share amount | $ (0.32) |

The following options and warrants outstanding at December 31, 2004 and 2003 to purchase shares of common stock were excluded from diluted loss per share, because of their anti-dilutive effect:

| | Number of Options/Warrants | Range of Exercise Prices |
|---|---|---|
| For the three and nine months ended: | | |
| December 31, 2004 | 2,046,576 | $0.90 to $10.50 |
| December 31, 2003 | 1,752,264 | $0.90 to $10.50 |

**6. Shareholders Equity**

We apply 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.

We account 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, we record options at their fair value on the measurement date, which is typically the vesting date.

Consulting Agreements

On April 1, 2003, we executed a consulting agreement with CCRI Corporation (CCRI) to provide investor relations and development services. We pay CCRI 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. We fully amortized the fair value of the common stock and warrants in fiscal 2004. Stock-based compensation expense for the CCRI agreement for the three and nine-months ended December 31, 2003 aggregated $110,924 and $217,410, respectively. On April 1, 2004, we extended the agreement for one year. The monthly fee of $4,000 plus expenses remained the same.

On April 1, 2003, we executed a consulting agreement with Executive Advisory Group (EAG) to provide us with general management advice and guidance as well as strategic and tactical planning services. Mr. Sam B. Humphries, at that time a Director of the Company, is President of EAG. We paid EAG a monthly fee of $6,000 plus expenses and granted to EAG stock options to purchase 50,000 shares of common stock, exercisable at $2.80 per share. We fully amortized the fair value of the stock options in fiscal 2004. 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. On April 1, 2004, we extended the agreement. The monthly fee of $6,000 plus expenses remained the same. This agreement was terminated on January 1, 2005, the date Mr. Humphries was appointed President and Chief Executive Officer of our Company.

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**7. Stock-based Compensation**

Had we determined compensation cost based on the fair value at the grant date for our stock options issued to employees under SFAS 123, Accounting for Stock-Based Compensation, our net loss and per share amounts would have increased to the pro forma amounts shown below:

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| Net loss As reported | $ (344,011) | $ (500,125) | $ (1,119,976) | $ (1,427,344) |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards | (1,221,115) | (43,868) | (403,940) | (217,367) |
| Net loss Pro forma | $ (1,565,126) | $ (543,993) | $ (2,413,012) | $ (1,644,711) |
| Net loss per common share - As reported: Basic and diluted | $ (0.07) | $ (0.11) | $ (0.24) | $ (0.32) |
| Net loss per common share - Pro forma: Basic and diluted | $ (0.34) | $ (0.12) | $ (0.52) | $ (0.37) |

**8. Savings and Retirement Plans**

We sponsor various plans for eligible employees in the United States, the United Kingdom (UK), and The Netherlands. Our retirement savings plan in the United States conforms to Section 401(k) of the Internal Revenue Code and participation is available to substantially all employees. We may also make discretionary contributions ratably to all eligible employees. Our international subsidiaries have defined benefit retirement plans for eligible employees. These plans provide benefits based on each employee s years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. Our UK subsidiary s defined benefit plan accrued pension liability and periodic pension cost are not material to our consolidated financial statements. Pension plan assets are invested in insurance contracts.

The cost for our plan in The Netherlands includes the following components for the periods ended December 31, 2004 and 2003:

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| Gross service cost, net of employee contribution | $ 31,248 | $ 19,697 | $ 89,723 | $ 58,421 |
| Interest cost | 17,684 | 12,916 | 50,777 | 38,308 |
| Expected return on assets | (10,135) | (7,488) | (29,101) | (22,209) |
| Amortization | 3,491 | 1,984 | 10,024 | 5,885 |
| Net periodic retirement cost | $ 42,288 | $ 27,109 | $ 121,423 | $ 80,405 |

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Major assumptions used in the above calculations include:

| | Three Months Ended December 31, | | Nine Months Ended December 31, | |
|---|---|---|---|---|
| | 2004 | 2003 | 2004 | 2003 |
| Discount rate | 5.25% | 5.25% | 5.25% | 5.25% |
| Expected return on assets | 4.50% | 4.50% | 4.50% | 4.50% |
| Expected rate of increase in future compensation | | | | |
| General | 3% | 3% | 3% | 3% |
| Individual | 0%-3% | 0%-3% | 0%-3% | 0%-3% |

**9. Foreign Currency Translation**

All assets and liabilities are translated using period-end exchange rates and statements of operations items are translated using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders equity. We recognize foreign currency transaction gains and losses in our consolidated statements of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders equity.

We recognize exchange gains and losses 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 our subsidiaries), as well as their effect on the dollar denominated intercompany obligations between the Company and its foreign subsidiaries. All intercompany balances are revolving in nature and are not deemed to be long-term balances. For the three-months ended December 31, 2004 and 2003, we recognized foreign currency gains (losses) of $(6,478) and $11,697, respectively. For the nine-months ended December 31, 2004 and 2003, we recognized foreign currency gains (losses) of $(20,564) and $5,126, respectively.

**10. Income Tax Expense**

During the quarters ended December 31, 2004 and 2003, our Dutch subsidiaries recorded income tax expense of $86,311 and $120,914, respectively, as we have fully utilized our net operating loss carryforwards. For the nine months ended December 31, 2004 and 2003, our Dutch subsidiaries recorded income tax expense of $138,540 and $241,309, respectively. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions.

**11. Business Segment Information**

We sell Macroplastique®, a soft tissue bulking material, for the treatment of urinary incontinence. In addition, we market our soft tissue bulking material for additional indications, including for the treatment of vocal cord rehabilitation, fecal incontinence and soft tissue facial augmentation. At this time, we make sales only outside the United States. Our current objectives are to focus on obtaining U.S. regulatory approvals for Macroplastique and the I-Stop sling for treating stress urinary incontinence, or SUI, and on increasing market penetration and sales of Macroplastique for the treatment of SUI and vesicoureteral reflux and of PTQ Implants for the treatment of fecal incontinence in markets outside the U.S. We anticipate initiating marketing in the U.S. once we obtain the requisite approvals. Our Macroplastique product line accounted for 77% and 84%, respectively, of total net sales during the

2004 and 2003 nine-month periods presented. In addition, we sell specialized wound care products in The Netherlands and United Kingdom as a distributor.

Based upon the above, we operate in only one reportable segment consisting of medical products primarily for the urology market.

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Information regarding operations in different geographies for the three and nine-months ended December 31, 2004 and 2003 is as follows:

| | United States | The Netherlands | United Kingdom | Adjustments and Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Fiscal 2005** | | | | | |
| Sales to customers, three-months ended December 31, 2004 | $ | $ 1,394,658 | $ 391,419 | $ (176,385) | $ 1,609,692 |
| Sales to customers, nine-months ended December 31, 2004 | | 4,255,905 | 1,264,274 | (507,267) | 5,012,912 |
| Income tax expense, three-months ended December 31, 2004 | | 86,311 | | | 86,311 |
| Income tax expense, nine-months ended December 31, 2004 | | 138,540 | | | 138,540 |
| Net income (loss), three-months ended December 31, 2004 | (520,693) | 165,788 | 14,178 | (3,284) | (344,011) |
| Net income (loss), nine-months ended December 31, 2004 | (1,495,654) | 271,347 | 8,773 | 95,558 | (1,119,976) |
| Long-lived assets At December 31, 2004 | 294,293 | 832,063 | 14,961 | | 1,141,317 |
| **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 | | 120,914 | | | 120,914 |
| Income tax expense, nine-months ended December 31, 2003 | | 241,309 | | | 241,309 |
| Net income (loss), three-months ended December 31, 2003 | (500,277) | 224,701 | (119,116) | (105,433) | (500,125) |
| Net income (loss), nine-months ended December 31, 2003 | (1,308,535) | 466,079 | (358,445) | (226,443) | (1,427,344) |
| Long-lived asset At December 31, 2003 | 317,196 | 786,180 | 21,719 | | 1,125,095 |

**ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

We recommend that you read this Report on Form 10-QSB in conjunction with our Annual Report on Form 10-KSB for the year ended March 31, 2004.

**Forward-looking Statements**

We may from time to time make written or oral forward-looking statements , including our statements contained in this filing with the Securities and Exchange Commission and in our 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 , goal , continue , or other co terminology. By their very nature, forward-looking statements are subject to known and unknown risks and uncertainties relating to our future performance that may cause our actual results, performance, or achievements, 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.

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Our 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 our 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 our results, performance, or achievements to differ materially from that contained in our 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 our other filings with the Securities and Exchange Commission.

We do not undertake, nor assume obligation, to update any forward-looking statement that we may make from time to time.

**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. The products we sell 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 we expect future sales growth to be, derived from Macroplastique and related ancillary products designed for use by urologists, gynecologists, and uro-gynecologists for the primary treatment of stress urinary incontinence, or SUI, and for the treatment of vesicouretal reflex, or VUR, a condition in which urine flows backward from the bladder to the kidney. Macroplastique is comprised of soft, textured, solid, medical grade silicone elastomer implants suspended in a biocompatible carrier gel. Our minimally invasive procedure allows for Macroplastique to be placed in the tissue of the mid-urethra (in the case of SUI), and at the ureteral orifice (in the case of VUR). The implants act as a bulking material to restore urinary continence or to eliminate backward flow of urine from the bladder to the kidneys.

We are concluding a multi-center human clinical trial with our urethral bulking agent, Macroplastique, pursuant to an FDA Investigational Device Exemption as a minimally invasive, office-based procedure for treating female SUI. Based on this clinical trial data, we are seeking premarket approval of Macroplastique for treating female SUI.

In addition to the urological applications, we also market our implantable tissue bulking material outside the U.S. for reconstructive and cosmetic plastic surgery applications under the trade name Bioplastique Implants; fecal incontinence applications under the trade name PTQ Implants (formerly PTP Implants); and vocal cord rehabilitation under the trade name VOX Implants. In The Netherlands and the United Kingdom, we distribute certain wound care products on behalf of another company in accordance with an executed Distributor Agreement. Under the terms of the Distributor Agreement, we are not obligated to purchase any minimum level of wound care products. In the United Kingdom we are the exclusive distributor of I-Stop®, a tension-free mid-urethral sling, indicated for the treatment of female urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency (ISD).

Each of our products is CE marked, demonstrating compliance with European requirements for medical devices and allowing our products to be sold within the European Union and other countries that recognize CE marking. Our products are sold by a direct sales force in the United Kingdom, and by a network of distributors in numerous countries outside the U.S., including in Europe, Australia, Canada and Latin America.

In September 2004, we entered into a Manufacturing and Distribution Agreement with CL Medical SAS, Lyon, France, under which we have exclusive distribution rights in the United States for CL Medical s tension-free synthetic sling, the I-Stop sling. The I-Stop sling is currently sold in Europe for treating female SUI due to urethral hypermobility, which occurs when the urethra is no longer appropriately supported by the surrounding tissues and ligaments. We have agreed to purchase our entire requirement of product components from CL Medical and to purchase specified minimum amounts of product components during the first 5 years of the agreement. We are responsible for FDA clinical and regulatory requirements for the product. The agreement is for 6 years with an option to renew the agreement for successive 5-year terms. We expect to submit to the FDA a 510(k), or premarket notification application, with respect to the I-Stop sling in 2005.

Our current objectives are to focus on obtaining U.S. regulatory approvals of Macroplastique and the I-Stop sling for treating SUI and increasing market penetration and sales of our products in countries outside the U.S. We anticipate initiating marketing in the U.S. once we obtain the requisite FDA approvals.

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In December 2004, we signed a letter of intent to acquire CystoMedix, Inc, a privately held company, and to a pursue a merger of CystoMedix into a newly formed subsidiary of ours. CystoMedix developed and markets a proprietary neuromodulation product for patients suffering from overactive bladder symptoms, including urge incontinence. The Urgent® PC Neuromodulation System has received CE marking and FDA approval for sale within and outside the United States. The merger consideration is expected to consist of our common stock and cash.

Completion of the merger is subject to completion of our due diligence investigation, negotiation of a definitive agreement, approval by CystoMedix shareholders and other customary conditions. We expect the merger will be completed by March 31, 2005. However, we cannot be certain the merger will occur at all or, if the merger is completed, that the merger will achieve the benefits that we may anticipate.

**Critical Accounting Policies**

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the U.S., which require us to make estimates and assumptions in certain circumstances that affect amounts reported. In preparing these consolidated financial statements, we have made our best estimates and judgments of certain amounts, giving due consideration to materiality. We believe that of our significant accounting policies, the following are particularly important to the portrayal of our results of operations and financial position. They may require the application of a higher level of judgment by Uroplasty management, and as a result are subject to an inherent degree of uncertainty.

Revenue Recognition and Accounts Receivable. The Securities and Exchange Commission s Staff Accounting Bulletin ( SAB ) No. 104, Revenue Recognition in Financial Statements, provides guidance on the application of generally accepted accounting principles to selected revenue recognition issues. We believe our revenue recognition policies comply with SAB 104. We market and distribute our products through a network of distributors and through direct sales to end-users in the United Kingdom and The Netherlands. We recognize revenue upon shipment of product to our distributors and direct customers. We have no customer acceptance provisions or installation obligations. Our sales terms to our distributors and customers provide no right of return outside of our standard warranty, and payment terms consistent with industry standards apply. Sales terms and pricing to our distributors are governed by the respective distribution agreements. Our distribution partners purchase the Uroplasty products to meet sales demand of their end-user customers as well as to fulfill their internal requirements associated with the sales process and, if applicable, contractual purchase requirements under the respective distribution agreements. Internal and other requirements include purchases of products for training, demonstration and evaluation purposes, clinical evaluations, product support, establishing inventories, and meeting minimum purchase commitments. As a result, the level of our revenue during any period is not necessarily indicative of our distributors sales to end-user customers during that period, which are estimated not to be substantially different than our sales to those distributors in each of the last two years. Our distributors level of inventories of our products, their sales to end-user customers and their internal product requirements may impact our future revenue growth.

Inventories. We state inventories at the lower of cost or market using the first-in, first-out method. We provide reserves for slow moving and obsolete inventories based upon current and expected future product sales and the expected impact of product transitions or modifications. While we expect our sales to grow, a reduction in sales could reduce the demand for our products, and additional inventory reserves may be required.

Foreign Currency Translation/Transactions. The financial statements of our foreign subsidiaries were translated in accordance with the provisions of SFAS No. 52 Foreign Currency Translation. Under this Statement, we translate all assets and liabilities using period-end exchange rates, and we translate statements of operations items using average exchange rates for the period. We record the resulting translation adjustment within accumulated other comprehensive loss, a separate component of shareholders equity. We recognize foreign currency transaction gains and losses in the

statement of operations, including unrealized gains and losses on short-term intercompany obligations using period-end exchange rates, resulting in an increase in the volatility of our consolidated statements of operations. We recognize unrealized gains and losses on long-term intercompany obligations within accumulated other comprehensive loss, a separate component of shareholders equity.

Impairment of Long-Lived Assets. Long-lived assets at December 31, 2004 consist of property, plant and equipment. We review our long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. We measure the recoverability of assets to be held and used by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If we consider such assets impaired, we measure the impairment to be recognized by the amount by which the carrying amount of the assets exceeds the fair value of the assets. We report assets to be disposed of at the lower of the carrying amount or fair value less costs to sell.

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Set forth below is management s discussion and analysis of the financial condition and results of operations for the three and nine-months ended December 31, 2004 and 2003.

**Results of Operations**

**Three-month period ended December 31, 2004 compared to three-month period ended December 31, 2003**

Net Sales: In the third quarter ended December 31, 2004, net sales of all products were $1,609,692, representing a $162,021 or 11% increase when compared to net sales of $1,447,671 for the third quarter ended December 31, 2003. Excluding fluctuations in foreign currency exchange rates, we had a sales increase of approximately 2%, mainly attributed to increased prices. We believe our sales will increase as a result of the impact of all sales personnel and their focus on the execution of sales plans designed to expand our global market share in the specialties of both urinary and fecal incontinence. The Macroplastique product line accounts for 76% and 84% of total net sales, respectively, during the periods presented.

Gross Profit: Gross profit was $1,226,119 and $1,043,541 for the quarters ended December 31, 2004 and 2003, respectively, or 76% and 72% of net sales. Gross profit increased as a result of increased customer prices and currency fluctuations. Gross profit as a percentage of net sales in any one specific period will continue to fluctuate, based on the following factors: our unit sales, our utilization of manufacturing capacity, the mix of products sold with different gross margins, the mix of customers (and different discounts to them), the mix of direct sales versus sales through distributors (with higher margins on direct sales), and currency fluctuations. Historically, the gross margin has ranged from approximately 70-80% of net sales.

General and Administrative Expense: General and administrative ( G&A ) expenses increased from $493,905 during the third quarter of fiscal 2004 to $504,390 during the third quarter of fiscal 2005. The G&A expense increase related to increased salary costs of $39,000, a $50,000 increase in professional fees for accounting and legal, general price increases and fluctuations in foreign currency exchange rates. This increase was offset in part by decreases of $29,000 in consulting fees and $108,000 of shareholders expense. The decrease in both the consulting fees and the shareholders expense primarily relates to the $139,883 of stock-based compensation expense recognized in the third quarter of fiscal 2004. The increased salary costs relates to added personnel and increased salaries.

Research and Development Expense: Research and development ( R&D ) expenses increased $104,370, or 23%, from $454,349 during the third quarter of fiscal 2004 to $558,719 during the third quarter of fiscal 2005. The increase in R&D expense is due to quality and regulatory costs related to the development of our premarket approval (PMA) submission for U.S. market clearance for Macroplastique in the treatment of adult female stress urinary incontinence.

Selling and Marketing Expenses: Selling and marketing ( S&M ) costs decreased 15% from $487,619 during the third quarter of fiscal 2004 to $416,886 during the third quarter of fiscal 2005. The decrease resulted from a $34,000 decrease in personnel costs, a $19,000 decrease of automobile expense, mainly due to an early returned lease car in fiscal 2004, decreased costs of $11,000 relating to trade-shows, conventions and congresses. The decreased personnel costs relate to dismissal payment made in the third quarter of fiscal 2004. The timing of when trade shows and congresses take place caused the decrease in the costs.

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. Our financial results are subject to material fluctuations based on changes in currency exchange rates. Other income (expense) was $(3,824) and $13,121 for the third quarters ended December 31, 2004 and 2003, respectively. We recognize exchange gains and losses 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 our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between the Company and its foreign subsidiaries. We recognized foreign currency gains (losses) of $(6,478) and $11,697 for the third quarters ended December 31, 2004 and 2003, respectively.

Income Tax Expense: Our Dutch subsidiaries recorded income tax expense of $86,311 and $120,914 for the third quarter ended December 31, 2004 and 2003, respectively, as they have fully utilized their net operating loss carryforwards. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. We expect continued profits for our 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. For profits after January 1, 2005 the Dutch income tax rate is 27% for euro 22,689 of profit and 31.5% for the amount above euro 22,689.

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**Nine-month period ended December 31, 2004 compared to nine-month period ended December 31, 2003**

Net Sales: During the nine-months ended December 31, 2004, net sales of all products were $5,012,912, representing a $1,030,579 or 26% increase when compared to net sales of $3,982,333 for the nine months ended December 31, 2003. Excluding fluctuations in foreign currency exchange rates, we had a sales increase of approximately 16%. The sales increase is partly contributed by price increases, but mainly attributable by increased unit sales. We believe the continued increase in sales is related to the impact and execution of sales plans designed to expand our global market share in the specialties of both urinary and fecal incontinence. The Macroplastique product line accounts for 77% and 84% of total net sales, respectively, during the periods presented.

Gross Profit: Gross profit was $3,695,609 and $2,875,228 for the nine-months ended December 31, 2004 and 2003, respectively, or 74% and 72% of net sales. Gross profit increased as a result of increased customer prices and currency fluctuations. Gross profit as a percentage of net sales in any one specific period will continue to fluctuate, based on the following factors: our unit sales, our utilization of manufacturing capacity, the mix of products sold with different gross margins, the mix of customers (and different discounts to them), the mix of direct sales versus sales through distributors (with higher gross margins on direct sales), and currency fluctuations. Historically, the gross margin has ranged from approximately 70-80% of net sales.

General and Administrative Expense: General and administrative ( G&A ) expenses decreased from $1,450,447 during the nine-months ended December 31, 2003 to $1,403,762 during the same period of fiscal 2005. The G&A expense decrease related to decreases of $87,000 in consulting fees and $215,000 of shareholders expense. This decrease was offset by increased salary costs of $80,000, a $125,000 increase in professional fees for accounting and legal, general price increases and fluctuations in foreign currency exchange rates. The decrease in both the consulting fees and the shareholders expense primarily relates to the $304,290 of stock-based compensation expense recognized in the nine-months ended December 31, 2003. The increased salary costs relates to added personnel and increased salaries.

Research and Development Expense: Research and development ( R&D ) expenses increased $388,175, or 29%, from $1,336,313 during the nine months ended December 31, 2003 to $1,724,488 for the same period of fiscal 2005. The increase in R&D expense is primarily due to quality and regulatory costs related to the development of the Company s premarket approval (PMA) submission for U.S. market clearance for Macroplastique in the treatment of adult female stress urinary incontinence.

Selling and Marketing Expenses: Selling and marketing ( S&M ) costs increased 19% from $1,286,922 during the nine months ended December 31, 2003 to $1,535,642 for the same period of fiscal 2005. This increase resulted from a $159,000 increase in personnel costs, an additional $141,000 in costs relating to trade-shows, conventions and congresses, general price increases, and fluctuations in foreign currency exchange rates. The increase was offset by a decrease in promotional costs of $60,000. The increased personnel costs relate to the hiring of experienced sales personnel and increased salaries and bonuses.

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. Our financial results are subject to material fluctuations based on changes in currency exchange rates. Other income (expense) was $(13,153) and $12,419 for the nine months ended December 31, 2004 and 2003, respectively. We recognize exchange gains and losses 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 our subsidiaries), as well as their effect on the dollar denominated short-term intercompany obligations between the Company and its foreign subsidiaries. We recognized foreign currency gains (losses) of $(20,564) and $5,126 for the periods presented.

Income Tax Expense: Our Dutch subsidiaries recorded income tax expense of $138,540 and $241,309 for the periods presented, as they have fully utilized their net operating loss carryforwards. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. We expect continued profits for our 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. For profits after January 1, 2005 the Dutch income tax rate is 27% for euro 22,689 of profit and 31.5% for the amount above euro 22,689.

**Liquidity and Capital Resources**

As of December 31, 2004, our cash and cash equivalent balances totaled $1,885,757.

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At December 31, 2004, we had working capital of approximately $3.0 million. During the nine month period ended December 31, 2004, we used $1,034,426 of cash in operating activities, compared to $760,743 of cash used in the prior-year. The usage of cash was primarily attributable to the net loss incurred of $1,119,976. Accounts receivable, other current assets, accounts payable and accrued expenses fluctuated due to the timing of payments and fluctuations in foreign currency exchange rates. We recorded $304,290 of non-cash stock-based compensation expense during the nine months ended December 31, 2003.

We currently have 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 our accounts receivable and inventory balances at December 31, 2004 of $1,180,398 and $573,255, respectively. For the remainder of fiscal 2005, we do not anticipate any material capital expenditures.

Our 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 we sell and distribute our products. 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 our 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 our cash flow and results of operations.

We expect to continue to incur significant costs for regulatory activities associated with obtaining regulatory approval in the United States for Macroplastique and the I-Stop sling. For the remainder of fiscal 2005, we have budgeted approximately $600,000 for our regulatory expenses. We currently expect that during fiscal 2006 selling and marketing expenses will continue to increase due to the anticipated launch of the Macroplastique and I-Stop products in the United States. In addition, we currently expect general and administrative expenses in fiscal 2006 to increase due to the implementation of Section 404 of the Sarbanes-Oxley Act of 2002.

We believe that current resources and the funds generated from sale of our products outside the U.S. will be adequate to meet our cash flow needs, including regulatory activities associated with existing products, through at least the first quarter of fiscal 2006. Ultimately, we will need to achieve profitability and positive cash flows from operations and to raise additional debt or equity financing to fund our operations and grow our business.

Repayments of our contractual obligations, consisting of royalties, notes payable, and operating leases, are summarized below:

| | Payments Due by Period | | | |
|---|---|---|---|---|
| | Total | Remainder of Fiscal 2005 | Fiscal 2006 | Fiscal 2007 and Thereafter |
| Minimum royalty payments | $ 365,000 | 13,500 | 104,000 | 247,500 |
| Notes payable | 539,669 | 11,640 | 46,560 | 481,469 |
| Operating lease commitments | 439,877 | 85,500 | 253,364 | 101,013 |
| Total contractual obligations | $ 1,344,546 | 110,640 | 403,924 | 829,982 |

Uroplasty has a pension plan covering 17 employees in The Netherlands, reported as a defined benefit plan. We pay premiums to an insurance company to fund annuities for these employees. However, we are responsible for funding

additional annuities based on continued service and future salary increases.

We are obligated to pay royalties of 5% of net sales in the U.S. of Macroplastique products with a minimum of $50,000 per year. The duration of this royalty agreement is through May 1, 2006. Under another royalty agreement we pay royalties, in the aggregate, of three to five percent of net sales of Macroplastique, Bioplastique, and PTQ Implants subject to a monthly minimum of $4,500. The royalties payable under this Agreement will continue until the patent referenced in the Agreement expires in 2010. Under a license agreement for the Macroplastique Implantation System, we pay a royalty of 10 British pounds for each unit sold during the life of the patent.

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**ITEM 3. CONTROLS AND PROCEDURES.**

Disclosure Controls and Procedures. Within the 90 days prior to the date of this report, our Principal Executive Officer and Principal Financial 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.

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PART II. OTHER INFORMATION

Except as indicated below, none of the items contained in PART II of Form 10-QSB are applicable to us for the three months ended December 31, 2004.

**ITEM 6. EXHIBITS.**

(a) Exhibits

10.1 Employment Agreement between Uroplasty, Inc. and Sam B. Humphries dated January 1, 2005

10.2 Employment and Consulting Agreement between Uroplasty, Inc. and Daniel G. Holman dated January 1, 2005

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

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

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**SIGNATURES**

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

UROPLASTY, INC.

Date: February 11, 2005 by: /s/ SAM B. HUMPHRIES

Sam B. Humphries
President and Chief Executive Officer

Date: February 11, 2005 by: /s/ DANIEL G. HOLMAN

Daniel G. Holman
Chief Financial Officer