

UROPLASTY INC  
Form 10QSB  
August 23, 2004

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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 June 30, 2004**

**Commission File No. 000-20989**

**UROPLASTY, INC.**

(Name of Small Business Issuer in its Charter)

<b>Minnesota, U.S.A.</b>	<b>41-1719250</b>
(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  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 August 2, 2004 was \$10,446,339.

The number of shares outstanding of the issuer's only class of common stock on August 2, 2004 was 4,659,865.

Transitional Small Business Disclosure Format:

YES  NO

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## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

## UROPLASTY, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	<b>June 30, 2004</b>	<b>March 31, 2004</b>
	<u>(unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$2,502,202	\$2,697,670
Accounts receivable, net	1,014,695	1,065,176
Inventories	469,102	519,130
Other	247,530	235,078
	<u>                    </u>	<u>                    </u>
Total current assets	4,233,529	4,517,054
Property, plant, and equipment, net	1,065,876	1,071,116
Intangible assets, net	47,229	51,495
Deferred tax assets	108,636	123,893
	<u>                    </u>	<u>                    </u>
Total assets	<u>\$5,455,270</u>	<u>\$5,763,558</u>

See accompanying notes to consolidated financial statements.

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## UROPLASTY, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	<u>June 30, 2004</u>	<u>March 31, 2004</u>
	(unaudited)	
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 220,977	\$ 225,315
Income tax payable	128,817	101,562
Accrued liabilities	427,969	475,957
Current maturities long-term debt	41,905	42,301
	<u>819,668</u>	<u>845,135</u>
Total current liabilities		
Long-term debt less current maturities	464,760	479,720
Accrued pension liability	333,469	334,470
	<u>1,617,897</u>	<u>1,659,325</u>
Total liabilities		
Shareholders' equity:		
Common stock \$.01 par value; 20,000,000 shares authorized, 4,602,033 and 4,584,802 shares issued and outstanding at June 30, 2004 and March 31, 2004, respectively	46,020	45,848
Additional paid-in capital	9,171,538	9,130,580
Accumulated deficit	(5,041,981)	(4,756,622)
Accumulated other comprehensive loss	(338,204)	(315,573)
	<u>3,837,373</u>	<u>4,104,233</u>
Total shareholders' equity		
Total liabilities and shareholders' equity	<u>\$ 5,455,270</u>	<u>\$ 5,763,558</u>

See accompanying notes to consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(Unaudited)

	<b>Three Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>
		<b>(restated)</b>
Net sales	\$ 1,752,496	\$ 1,359,589
Cost of goods sold	463,558	396,971
	<u>1,288,938</u>	<u>962,618</u>
Gross profit		
	<u>1,288,938</u>	<u>962,618</u>
Operating expenses		
General and administrative	391,112	467,229
Research and development	580,053	429,956
Selling and marketing	527,957	424,365
	<u>1,499,122</u>	<u>1,321,550</u>
Operating loss	<u>(210,184)</u>	<u>(358,932)</u>
Other income (expense)		
Interest income	5,879	10,509
Interest expense	(5,184)	(5,844)
Foreign currency exchange loss	(9,411)	(2,361)
	<u>(8,716)</u>	<u>2,304</u>
Loss before income taxes	(218,900)	(356,628)
Income tax expense	66,459	92,056
	<u>(285,359)</u>	<u>(448,684)</u>
Net loss	<u>\$ (285,359)</u>	<u>\$ (448,684)</u>
Basic loss per common share	\$ (0.06)	\$ (0.10)

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Diluted loss per common share	\$ (0.06)	\$ (0.10)
Weighted average common shares outstanding:		
Basic	4,591,136	4,483,971
Diluted	4,591,136	4,483,971

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## UROPLASTY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

Three Months ended June 30, 2004 and 2003

(Unaudited)

	<b>2004</b>	<b>2003</b>
		<b>(restated)</b>
Cash flows from operating activities:		
Net loss	\$ (285,359)	\$ (448,684)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation and amortization	40,822	37,362
Loss on disposal of assets	2,281	
Stock-based consulting expense		82,204
Changes in operating assets and liabilities:		
Accounts receivable	38,924	153,868
Inventories	39,201	(26,965)
Other current assets	(15,511)	(25,948)
Deferred tax assets	16,220	7,314
Accounts payable	(2,301)	72,885
Accrued liabilities	(16,849)	(25,979)
Accrued pension liability	(3,851)	25,415
Additional pension liability	1,824	(2,222)
	<u>          </u>	<u>          </u>
Net cash used in operating activities	<u>(184,599)</u>	<u>(150,750)</u>
Cash flows from investing activities:		
Payments for property, plant and equipment	(38,748)	(27,107)
Payments relating to intangible assets	(2,656)	(5,167)
	<u>          </u>	<u>          </u>
Net cash used in investing activities	<u>(41,404)</u>	<u>(32,274)</u>
Cash flows from financing activities:		
Repayment of long-term debt	(10,381)	(9,794)
Net proceeds from issuance of stock	41,130	
	<u>          </u>	<u>          </u>
Net cash provided by (used in) financing activities	<u>30,749</u>	<u>(9,794)</u>
Effect of exchange rates on cash and cash equivalents	<u>(214)</u>	<u>13,966</u>

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Net decrease in cash and cash equivalents	(195,468)	(178,852)
Cash and cash equivalents at beginning of period	<u>2,697,670</u>	<u>3,375,981</u>
Cash and cash equivalents at end of period	<u>\$2,502,202</u>	<u>\$3,197,129</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 5,496	\$ 6,729
Cash paid during the period for income taxes	24,133	
Supplemental disclosure of non-cash financing and investing activities:		
None.		

See accompanying notes to consolidated financial statements.

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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, 2004.

The consolidated financial statements presented herein as of June 30, 2004 and for the three-month periods ended June 30, 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.

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 of which more fully described in the Company s Annual Report on Form 10-KSB for the year ended March 31, 2004. Based upon the Company s review, management has determined that these policies remain its most critical accounting policies for the three-month period ended June 30, 2004, and has made no changes to these policies during fiscal 2005.

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

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. Restatements**

During the fiscal 2004 year end close process, the Company determined that its pension plan, covering 18 employees in The Netherlands, had historically been reported as a defined contribution plan, but should have been reported as a defined benefit plan. The Company pays premiums to an insurance company to fund annuities for these employees. However, the Company is responsible for funding additional annuities based on continued service and future salary increases. Furthermore, the Company discovered an error in how the effect of exchange rates on cash and cash

equivalents was recorded in the Statement of Cash Flows. In this Form 10-QSB, the Company has restated its first quarter of fiscal 2004 consolidated results of operations, the first quarter of fiscal 2004 consolidated statement of cash flows and related footnote disclosures for the impact of accounting for the pension plan as a defined benefit plan and for the correction of the effect of exchange rates on cash and cash equivalents as follows:

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	<b>Three Months Ended June 30, 2003</b>	
	<b>As previously reported</b>	<b>As restated</b>
<b>STATEMENT OF OPERATIONS</b>		
<b>DATA:</b>		
Cost of goods sold	\$ 405,587	\$ 396,971)
Operating expenses		
General and administrative	465,276	467,229
Research and development	438,573	429,956
Selling and marketing	422,410	424,365
Operating loss	(372,257)	(358,932)
Loss before income taxes	(369,953)	(356,628)
Income tax expense	80,166	92,056
Net loss	(450,119)	(448,684)
Net income per common share		
Basic	\$ (0.10)	\$ (0.10)
Diluted	\$ (0.10)	\$ (0.10)
<b>CASH FLOW DATA:</b>		
Net cash used in operating activities	\$(240,900)	\$(150,750)
Effect of exchange rates on cash and cash equivalents	104,116	13,966

**4. Inventories**

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

	<b>June 30, 2004</b>	<b>March 31, 2004</b>
Raw materials	\$152,318	\$138,920
Work-in-process	110,855	110,511
Finished goods	205,929	269,699
	<u>          </u>	<u>          </u>
	\$469,102	\$519,130
	<u>          </u>	<u>          </u>

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

	<b>Three Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>
		<b>(restated)</b>
Net loss	\$(285,359)	\$(448,684)
Items of other comprehensive income (loss):		
Translation adjustment	(23,572)	61,993
Additional pension liability	941	(52,159)
	<hr/>	<hr/>
Comprehensive loss	\$(307,990)	\$(438,850)
	<hr/>	<hr/>

**6. 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-months ended June 30, 2004 and 2003 was calculated using the treasury-stock method to compute the weighted average common stock outstanding assuming the conversion of dilutive potential common shares.

	<b>Basic Loss Per Share</b>	<b>Effect of Dilutive Securities</b>	<b>Diluted Loss Per Share</b>
	<hr/>	<hr/>	<hr/>
For the three months ended: June 30, 2004			
Net loss	\$ (285,359)		\$ (285,359)
Weighted average shares	4,591,136		4,591,136
	<hr/>		<hr/>
Per share amount	\$ (0.06)		\$ (0.06)
	<hr/>		<hr/>
For the three months ended: June 30, 2003			

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Net loss (restated)	\$ (448,684)	\$ (448,684)
Weighted average shares	<u>4,483,971</u>	<u>4,483,971</u>
Per share amount (restated)	<u>\$ (0.10)</u>	<u>\$ (0.10)</u>

The following options and warrants outstanding at June 30, 2004 and 2003 to purchase shares of common stock were excluded from diluted loss per share, because of their anti-dilutive effect:

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	<b>Number of Options/Warrants</b>	<b>Range of exercise prices</b>
For the three months ended:		
June 30, 2004	1,710,069	\$0.90 to \$10.50
June 30, 2003	1,763,458	\$0.90 to \$10.50

**7. 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 CCRI 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 fair value of the common stock and warrants was fully amortized in fiscal 2004. Stock-based compensation expense for CCRI agreement for the three-months ended June 30, 2003 aggregated \$53,242. On April 1, 2004, the agreement was extended for one year. The monthly fee of \$4,000 plus expenses remained the same.

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 fair value of the stock options was fully amortized in fiscal 2004. Stock-based compensation expense for the EAG agreement for the three-months ended June 30, 2003 aggregated \$28,962. On April 1, 2004, the agreement was extended for one year. The monthly fee of \$6,000 plus expenses remained the same.

**8. Stock-based Compensation**

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 loss would have increased to the pro forma amounts shown below:



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	<b>Three Months Ended June 30,</b>	
	<b>2004</b>	<b>2003</b>
		<b>(restated)</b>
Net loss As reported	\$(285,359)	\$(448,684)
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	<u>(36,007)</u>	<u>(90,925)</u>
Net loss Pro forma	<u>\$ (321,366)</u>	<u>\$ (539,609)</u>
Net loss per common share As reported:		
Basic	\$ (0.06)	\$ (0.10)
Diluted	\$ (0.06)	\$ (0.10)
Net loss per common share Pro forma:		
Basic	\$ (0.07)	\$ (0.12)
Diluted	\$ (0.07)	\$ (0.12)

**9. Savings and Retirement Plans**

The Company sponsors various plans for eligible employees in the United States, the United Kingdom (UK), and The Netherlands. The Company's 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. The Company may also make discretionary contributions ratably to all eligible employees. The Company's international subsidiaries have defined benefit retirement plans for eligible employees. These plans provide benefits based on the employee's years of service and compensation during the years immediately preceding retirement, termination, disability, or death, as defined in the plans. The Company's UK subsidiary defined benefit plan accrued pension liability and periodic pension cost are not material to the Company's consolidated financial statements. Pension plan assets are invested in insurance contracts.

The cost for the Company's plan in The Netherlands includes the following components for the periods ended June 30, 2004 and 2003:

**Three Months Ended  
June 30,**

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	<u>2004</u>	<u>2003</u>
		<b>(restated)</b>
Gross service cost, net of employee contribution	\$29,076	\$19,480
Interest cost	16,455	12,774
Expected return on assets	(9,431)	(7,405)
Amortization	<u>3,248</u>	<u>1,962</u>
Net periodic retirement cost	<u>\$39,348</u>	<u>\$26,810</u>

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Major assumptions used in the above calculations include:

	<b>Three Months Ended June 30,</b>	
	<b>2004</b>	<b>2003 (restated)</b>
Discount rate	5.25%	5.25%
Expected return on assets	4.50%	4.50%
Expected rate of increase in future compensation		
General	3%	3%
Individual	0%-3%	0%-3%

**10. 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. The resulting translation adjustment is recorded within accumulated other comprehensive loss, a separate component of shareholders' equity. Foreign currency transaction gains and losses are recognized currently in the consolidated statements of operations, including unrealized gains and losses on short-term inter-company obligations using period-end exchange rates. Unrealized gains and losses on long-term intercompany obligations are recognized within accumulated other comprehensive loss, a separate component of shareholders' equity.

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. The Company recognized net foreign currency losses of \$9,411 and \$2,361 for the quarters ended June 30, 2004 and 2003, respectively.

**11. Income Tax Expense**

During the quarters ended June 30, 2004 and 2003, the Company's Dutch subsidiaries recorded income tax expense of \$66,459 and \$92,056, 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.

**12. Business Segment Information**

The Company sells Macroplastique and the related ancillary products used for soft-tissue augmentation for the treatment of 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 and 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 79% and 84% of total net sales during the periods presented.

Based upon the above, the Company operates 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-months ended June 30, 2004 and 2003 is as follows:

	<b>United States</b>	<b>The Netherlands</b>	<b>United Kingdom</b>	<b>Adjustments and eliminations</b>	<b>Consolidated</b>
<b>Fiscal 2004</b>					
Sales to customers	\$	1,445,453	459,831	(152,788)	1,752,496
Income tax expense	\$	66,459			66,459
Net income (loss)	\$(554,046)	133,251	14,332	121,104	(285,359)
Long-lived assets At June 30, 2004	\$ 327,924	767,538	17,643		1,113,105
<b>Fiscal 2003 (restated)</b>					
Sales to customers	\$	1,214,581	332,352	(187,344)	1,359,589
Income tax expense	\$	92,056			92,056
Net income (loss)	\$(319,365)	187,738	(147,080)	(169,977)	(448,684)
Long-lived assets At June 30, 2003	\$ 151,362	739,883	25,155		916,400

**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, 2004.

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

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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.

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### **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 primary 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, textured, vulcanized, medical grade silicone elastomer implants suspended in a biocompatible carrier gel. Our minimally invasive procedure allows for Macroplastique to be placed in the soft tissue of the mid-urethra (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 PTQ Implants (formerly PTP Implants); and vocal cord rehabilitation under the trade name VOX Implants. In The Netherlands and the United Kingdom, the Company 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 sold by direct sales forces in the United Kingdom, and by a network of distributors in numerous countries outside the U.S., including Europe, Australia, Canada 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 current objectives are to focus on sales and marketing activities designed to increase market penetration and sales of Macroplastique for SUI and VUR, and of PTQ Implants for fecal incontinence applications 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.

### **Critical Accounting Policies**

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the U.S., 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 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 Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition provides guidance on the application of generally accepted accounting principles to selected revenue recognition issues, and the Company's revenue recognition policies are in compliance with SAB 104. The Company markets and distributes its products through a network of distributors and through direct sales to end-users in the United Kingdom and The Netherlands. The Company recognizes revenue upon shipment of product to its distributors and direct customers. There are no customer acceptance provisions or Company installation

obligations. The Company's sales terms to its distributors and customers provide no right of return outside of the Company's standard warranty, and payment terms consistent with industry standards apply. Sales terms and pricing to the Company's distributors are governed by the respective distribution agreements. The Company's distribution partners purchase the Company's 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, meeting minimum purchase commitments. As a result, 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.



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**Inventories.** Inventories are stated at the lower of cost or market using the first-in, first-out method. Reserves for slow moving and obsolete inventories are provided based upon current and expected future product sales and the expected impact of product transitions or modifications. While the Company expects its sales to grow, a reduction in its sales could reduce the demand for the Company's products, and additional inventory reserves may be required.

**Foreign Currency Translation/Transactions.** The financial statements of the Company's foreign subsidiaries were translated in accordance with the provisions of SFAS No. 52 Foreign Currency Translation. Under this Statement, 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. The resulting translation adjustment is recorded within accumulated other comprehensive loss, a separate component of shareholders' equity. 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 Consolidated 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.** Long-lived assets at June 30, 2004 consist of property, plant and equipment. The Company reviews its long-lived assets for impairment whenever events or business circumstances indicate that the carrying amount of an asset may not be recoverable. 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. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

Set forth below is management's discussion and analysis of the financial condition and results of operations for the three-month periods ended June 30, 2004 and 2003.

## **Results of Operations**

**Net Sales:** In the first quarter ended June 30, 2004, net sales of all products were \$1,752,496, representing a \$392,907 or 29% increase when compared to net sales of \$1,359,589 for the first quarter ended June 30, 2003. Excluding fluctuations in foreign currency exchange rates, there was a sales increase of approximately 20%. Management believes the increase in sales is related to the impact of the hiring of experienced sales directors and representatives, and their focus of initiating sales plans to increase our market share within the global distributor markets and to increase sales penetration to surgeons in our direct market in the United Kingdom. The Macroplastique product line accounts for 79% and 84% of total net sales during the periods presented.

**Gross Profit:** Gross profit was \$1,288,938 and \$962,618 for the quarter ended June 30, 2004 and 2003, respectively, or 74% 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 varied between approximately 70-80% of net sales.

**General and Administrative Expense:** General and administrative ( G&A ) expenses decreased from \$467,229 during the first quarter of fiscal 2004 to \$391,112 during the first quarter of fiscal 2005. Decreased consulting fees and shareholders expense, offset by increased salary costs, combined with general price increases and fluctuations in foreign currency exchange rates caused the decrease 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 CCRI Corporation to provide investor relations and development services.

Research and Development Expense: Research and development ( R&D ) expenses increased \$150,097, or 35%, from \$429,956 during the first quarter of fiscal 2004 to \$580,053 during the first quarter of fiscal 2005. The increase in R&D expense is related to clinical, 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 24% from \$424,365 during the first quarter of fiscal 2004 to \$527,957 during the first quarter of fiscal 2005. The increase resulted from travel costs and costs relating to trade-shows, conventions and congresses, marketing materials, general price increases, and fluctuations in foreign currency exchange rates.

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**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 (expense) was \$(8,716) and \$2,304 for the first quarter ended June 30, 2004 and 2003, respectively. The majority of the difference between periods was due to foreign currency exchange gains. 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. The Company recognized foreign currency losses of \$9,411 and \$2,361 for the first quarter ended June 30, 2004 and 2003, respectively.

**Income Tax Expense:** The Company's Dutch subsidiaries recorded income tax expense of \$66,459 and \$92,056 for the first quarter ended June 30, 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. 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 June 30, 2004, the Company's cash and cash equivalent balances totaled \$2,502,202.

At June 30, 2004, the Company had working capital of approximately \$3.4 million. During the quarter ended June 30, 2004, \$184,599 of cash was used in operating activities, compared to \$150,750 of cash used in the prior year. The usage of cash was primarily attributable to the net loss incurred of \$285,359, compared to a loss of \$448,684 in the prior year. Accounts receivable, other current assets, accounts payable and accrued expenses fluctuated due to the timing of payments and fluctuations in foreign currency exchange rates.

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 June 30, 2004 of \$1,014,695 and \$469,102, respectively. For fiscal 2005, 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.



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Repayments on the Company's contractual obligations, consisting of royalties, notes payable, and operating leases, are summarized below:

	<b>Payments due by period</b>			<b>Fiscal 2007 and thereafter</b>
	<b>Total</b>	<b>Remainder of Fiscal 2005</b>	<b>Fiscal 2006</b>	
Minimum royalty payments	\$ 392,000	40,500	104,000	247,500
Notes payable	506,653	31,421	41,894	433,338
Operating lease commitments	619,442	285,985	240,817	92,640
<b>Total contractual obligations</b>	<b>\$1,518,095</b>	<b>357,906</b>	<b>386,711</b>	<b>773,478</b>

The Company has a pension plan covering 18 employees in The Netherlands, reported as a defined benefit plan. The Company pays premiums to an insurance company to fund annuities for these employees. However, the Company is responsible for funding additional annuities based on continued service and future salary increases.

The Company is 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 the Company pays 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 the Company pays a royalty of 10 British pounds for each unit sold during the life of the patent.

**ITEM 3. CONTROLS AND PROCEDURES.**

**Disclosure Controls and Procedures.** At the end of the period covered by 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.

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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 the Company for the three months ended June 30, 2004.

**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 August 23, 2004

(b) Reports on Form 8-K

On June 14, 2004, the Company announced that KPMG, the Company's certifying accountant, declined to stand for reelection and that the client-auditor relationship between the Company and KPMG LLP will cease upon completion of KPMG's audit of the Company's consolidated financial statements as of and for the year ended March 31, 2004 and the issuance of their report thereon.

On June 29, 2004, the Company filed an extension of time to file its annual report on Form 10KSB.

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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: August 23, 2004

by: /s/ DANIEL G. HOLMAN  
Daniel G. Holman  
President, Chief Executive Officer,  
Chief Financial Officer and Director  
(Principal Executive and Financial Officer)

Date: August 23, 2004

by: /s/ ARIE J. KOOLE  
Arie J. Koole  
Controller (Principal Accounting Officer)

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