

UROPLASTY INC  
Form 10QSB  
November 12, 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 September 30, 2004**

**Commission File No. 000-20989**

**UROPLASTY, INC.**

(Name of Small Business Issuer in its Charter)

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

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

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

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

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

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

YES  NO

The number of shares outstanding of the issuer's only class of common stock on November 1, 2004 was 4,662,731.

Transitional Small Business Disclosure Format:

YES  NO

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## UROPLASTY, INC. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

	<b>September 30, 2004</b> <b>(unaudited)</b>	<b>March 31, 2004</b>
	<hr/>	<hr/>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 294,932	\$ 225,315
Income tax payable	127,479	101,562
Accrued liabilities	441,018	475,957
Current maturities of long-term debt	42,717	42,301
	<hr/>	<hr/>
Total current liabilities	906,146	845,135
Long-term debt less current maturities	463,088	479,720
Accrued pension liability	341,568	334,470
	<hr/>	<hr/>
Total liabilities	1,710,802	1,659,325
	<hr/>	<hr/>
Shareholders' equity:		
Common stock \$.01 par value; 20,000,000 shares authorized, 4,662,731 and 4,584,802 shares issued and outstanding at September 30, 2004 and March 31, 2004, respectively	46,627	45,848
Additional paid-in capital	9,291,913	9,130,580
Accumulated deficit	(5,532,587)	(4,756,622)
Accumulated other comprehensive loss	(284,567)	(315,573)
	<hr/>	<hr/>
Total shareholders' equity	3,521,386	4,104,233
	<hr/>	<hr/>
Total liabilities and shareholders' equity	\$ 5,232,188	\$ 5,763,558
	<hr/>	<hr/>

See accompanying notes to the interim consolidated financial statements.

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## UROPLASTY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003	2004	2003
		<b>(restated)</b>		<b>(restated)</b>
Net sales	\$ 1,650,724	\$ 1,175,073	\$ 3,403,220	\$ 2,534,662
Cost of goods sold	470,172	306,004	933,730	702,975
	<u>1,180,552</u>	<u>869,069</u>	<u>2,469,490</u>	<u>1,831,687</u>
Gross profit				
Operating expenses				
General and administrative	508,260	489,313	899,372	956,542
Research and development	585,716	452,008	1,165,769	881,964
Selling and marketing	590,799	374,938	1,118,756	799,303
	<u>1,684,775</u>	<u>1,316,259</u>	<u>3,183,897</u>	<u>2,637,809</u>
Operating loss	<u>(504,223)</u>	<u>(447,190)</u>	<u>(714,407)</u>	<u>(806,122)</u>
Other income (expense)				
Interest income	9,199	6,608	15,078	17,117
Interest expense	(5,137)	(5,404)	(10,321)	(11,248)
Foreign currency exchange loss	(4,675)	(4,210)	(14,086)	(6,571)
	<u>(613)</u>	<u>(3,006)</u>	<u>(9,329)</u>	<u>(702)</u>
Loss before income taxes	<u>(504,836)</u>	<u>(450,196)</u>	<u>(723,736)</u>	<u>(806,824)</u>
Income tax expense (benefit)	<u>(14,230)</u>	<u>28,339</u>	<u>52,229</u>	<u>120,395</u>
Net loss	<u>\$ (490,606)</u>	<u>\$ (478,535)</u>	<u>\$ (775,965)</u>	<u>\$ (927,219)</u>

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Basic and diluted loss per common share	\$ (0.11)	\$ (0.11)	\$ (0.17)	\$ (0.21)
Weighted average common shares outstanding:				
Basic and diluted	4,653,870	4,487,222	4,622,728	4,485,606

See accompanying notes to the interim consolidated financial statements.

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## UROPLASTY, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

Six Months Ended September 30, 2004 and 2003  
(Unaudited)

	<b>Six Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
		<b>(restated)</b>
Cash flows from operating activities:		
Net loss	\$ (775,965)	\$ (927,219)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	80,503	76,710
Loss on disposal of assets	2,281	
Stock-based consulting expense		164,407
Changes in operating assets and liabilities:		
Accounts receivable	(64,874)	279,785
Inventories	4,992	(9,466)
Other current assets	(17,345)	(3,873)
Deferred tax assets	(30,094)	(36,972)
Accounts payable	67,952	119,679
Accrued liabilities	(10,566)	(4,848)
Accrued pension liability	(1,552)	18,261
Additional pension liability	1,824	(2,222)
	<hr/>	<hr/>
Net cash used in operating activities	(742,844)	(325,758)
	<hr/>	<hr/>
Cash flows from investing activities:		
Payments for property, plant and equipment	(47,773)	(56,377)
Payments for intangible assets	(5,512)	(15,080)
	<hr/>	<hr/>
Net cash used in investing activities	(53,285)	(71,457)
	<hr/>	<hr/>
Cash flows from financing activities:		
Repayment of long-term debt	(20,761)	(19,589)
Net proceeds from issuance of stock	162,112	9,602
	<hr/>	<hr/>
Net cash provided by (used in) financing activities	141,351	(9,987)



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	<u>                    </u>	<u>                    </u>
Effect of exchange rates on cash and cash equivalents	25,014	27,371
	<u>                    </u>	<u>                    </u>
Net decrease in cash and cash equivalents	(629,764)	(379,831)
Cash and cash equivalents at beginning of period	2,697,670	3,375,981
	<u>                    </u>	<u>                    </u>
Cash and cash equivalents at end of period	\$2,067,906	\$2,966,150
	<u>                    </u>	<u>                    </u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest	\$ 10,930	\$ 12,095
Cash paid during the period for income taxes	60,362	

See accompanying notes to the interim consolidated financial statements.

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UROPLASTY, INC. AND SUBSIDIARIES

NOTES TO THE INTERIM CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

**1. Basis of Presentation**

We have prepared our 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 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 consolidated financial statements presented herein as of September 30, 2004 and for the three and six-months periods ended September 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.

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 six-month periods ended September 30, 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 undertaking FDA investigational clinical trials. Based on our current plans, we intend to launch our 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, 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 R&D activities, associated with existing products and markets through fiscal 2005. Ultimately, we will need to achieve profitability and positive cash flows from operations or obtain additional debt or equity financing to fund our operations.

**3. Restatements**

During the fiscal 2004 year end close process, we determined that our pension plan, covering 17 employees in The Netherlands, had historically been reported as a defined contribution plan, but should have been 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.

Contemporaneously, we also discovered an error in how we recorded the effect of exchange rates on cash and cash equivalents in our statement of cash flows. Historically, we prepared the statement of cash flows on a consolidated basis using period-end exchange rates. Instead, we should have prepared the statement of cash flows on an entity basis using average exchange rates in accordance with paragraph 25 of FAS 95.

In this Form 10-QSB, we have restated our consolidated results of operations for the three and six-month periods ended September 30, 2003, our consolidated statement of cash flows for the six-month period ended September 30, 2003, 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 September 30, 2003</b>		<b>Six Months Ended September 30, 2003</b>	
	<b>As Previously Reported</b>	<b>As Restated</b>	<b>As Previously Reported</b>	<b>As Restated</b>
<b>STATEMENT OF OPERATIONS DATA:</b>				
Cost of goods sold	\$ 274,186	\$ 306,004	\$ 679,773	\$ 702,975
Operating expenses				
General and administrative	456,769	489,313	922,045	956,542
Research and development	420,190	452,008	858,763	881,964
Selling and marketing	342,394	374,938	764,804	799,303
Operating loss	(318,466)	(447,190)	(690,723)	(806,122)
Loss before income taxes	(321,472)	(450,196)	(691,425)	(806,824)
Income tax expense	72,248	28,339	152,414	120,395
Net loss	\$(393,720)	\$(478,535)	\$(843,839)	\$(927,219)
Net loss per common share				
Basic	\$ (0.09)	\$ (0.11)	\$ (0.19)	\$ (0.21)
Diluted	\$ (0.09)	\$ (0.11)	\$ (0.19)	\$ (0.21)
<b>CASH FLOW DATA:</b>				
Net cash used in operating activities			\$(432,293)	\$(325,758)
Net cash used in investing activities			(71,311)	(71,457)
Net cash used in financing activities			(9,868)	(9,987)
Effect of exchange rates on cash and cash equivalents			\$ 133,641	\$ 27,371

**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>September 30, 2004</b>	<b>March 31, 2004</b>
Raw materials	\$206,646	\$138,920
Work-in-process	36,494	110,511
Finished goods	275,878	269,699
	<u>\$519,018</u>	<u>\$519,130</u>

**Table of Contents****5. Comprehensive Loss**

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003	2004	2003
		<b>(restated)</b>		<b>(restated)</b>
Net loss	\$(490,606)	\$(478,535)	\$(775,965)	\$(927,219)
Items of other comprehensive income (loss):				
Translation adjustment	55,566	28,238	31,994	137,389
Additional pension liability	(1,929)	(690)	(988)	(3,415)
	<u>          </u>	<u>          </u>	<u>          </u>	<u>          </u>
Comprehensive loss	<u>\$ (436,969)</u>	<u>\$ (450,987)</u>	<u>\$ (744,959)</u>	<u>\$ (793,245)</u>

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

Basic 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: September 30, 2004	
Net loss	\$ (490,606)
Weighted average shares	<u>4,653,870</u>
Per share amount	<u>\$ (0.11)</u>
For the three months ended: September 30, 2003	
Net loss (restated)	\$ (478,535)
Weighted average shares	<u>4,487,222</u>
Per share amount (restated)	\$ (0.11)

For the six months ended:  
September 30, 2004

Net loss	\$ (775,965)
Weighted average shares	<u>4,622,728</u>

Per share amount	\$ <u>(0.17)</u>
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	<b>Basic and Diluted Loss Per Share</b>
For the six months ended:	
September 30, 2003	
Net loss (restated)	\$ (927,219)
Weighted average shares	4,485,606
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Per share amount (restated)	\$ (0.21)
	<hr/>

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

	<b>Number of Options/Warrants</b>	<b>Range of Exercise Prices</b>
For the three and six months ended:		
September 30, 2004	1,647,571	\$0.90 to \$10.50
September 30, 2003	1,737,629	\$0.90 to \$10.50

**7. 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 six-months ended September 30, 2003 aggregated \$53,244 and \$106,486, 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, a

Director of the Company, is President of EAG. We pay 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. 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 six-months ended September 30, 2003 aggregated \$28,959 and \$57,921, respectively. On April 1, 2004, we extended the agreement for one year. The monthly fee of \$6,000 plus expenses remained the same.

### **8. 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:

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	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
Net loss As reported	\$ (490,606)	\$ (478,535)	\$ (775,965)	\$ (927,219)
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(35,914)	(82,574)	(71,921)	(173,499)
Net loss Pro forma	\$ (526,520)	\$ (561,109)	\$ (847,886)	\$ (1,100,718)
Net loss per common share As reported:				
Basic and diluted	\$ (0.11)	\$ (0.11)	\$ (0.17)	\$ (0.21)
Net loss per common share Pro forma:				
Basic and diluted	\$ (0.11)	\$ (0.13)	\$ (0.18)	\$ (0.25)

**9. 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 September 30, 2004 and 2003:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
Gross service cost, net of employee contribution	\$ 29,399	\$ 19,244	\$ 58,475	\$ 38,724
Interest cost	16,638	12,619	33,093	25,392

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Expected return on assets	(9,535)	(7,316)	(18,966)	(14,721)
Amortization	<u>3,285</u>	<u>1,939</u>	<u>6,533</u>	<u>3,901</u>
Net periodic retirement cost	<u>\$39,787</u>	<u>\$26,486</u>	<u>\$ 79,135</u>	<u>\$ 53,296</u>

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Major assumptions used in the above calculations include:

	Three Months Ended September 30,		Six Months Ended September 30,	
	2004	2003 (restated)	2004	2003 (restated)
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%

**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. 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 September 30, 2004 and 2003, we recognized foreign currency losses of \$4,675 and \$4,210, respectively. For the six-months ended September 30, 2003 and 2002, we recognized foreign currency losses of \$14,086 and \$6,571, respectively.

**11. Income Tax Expense**

During the quarters ended September 30, 2004 and 2003, our Dutch subsidiaries recorded income tax (benefit) expense of \$(14,230) and \$28,339, respectively, as we have fully utilized our net operating loss carryforwards. The U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. For the six-months ended September 30, 2004 and 2003, our Dutch subsidiaries recorded income tax expense of \$52,229 and \$120,395, respectively,

**12. Business Segment Information**

Uroplasty sells Macroplastique® and the related ancillary products to augment soft tissues for the purpose of treating urinary incontinence and vesicoureteral reflux. At this time, we make sales only outside the United States because we have not yet made submissions to the FDA for regulatory approval to market our products in the United States. Our current objectives are to focus on sales and marketing activities designed to increase market penetration and sales of Macroplastique for stress urinary incontinence (SUI) and for the treatment of vesicoureteral reflux (VUR), and of PTQ Implants (formerly PTP 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. We also sell injectable implant products outside the U.S. for soft-tissue augmentation for specific indications in otolaryngology and plastic surgery applications under the name Bioplastique in limited markets. Our Macroplastique product line accounts for 76% and 83%, respectively, of total net sales during the 2004 and 2003 six-month periods presented. In addition, we sell specialized wound care products in The Netherlands and United Kingdom as a distributor.

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

Information regarding operations in different geographies for the three and six-months ended September 30, 2004 and 2003 is as follows:

	<u>United States</u>	<u>The Netherlands</u>	<u>United Kingdom</u>	<u>Adjustments and Eliminations</u>	<u>Consolidated</u>
<b>Fiscal 2005</b>					
Sales to customers, three-months ended September 30, 2004	\$	\$1,415,794	\$ 413,024	\$(178,094)	\$1,650,724
Sales to customers, six-months ended September 30, 2004		2,861,247	872,855	(330,882)	3,403,220
Income tax benefit, three-months ended September 30, 2004		(14,230)			(14,230)
Income tax expense, six-months ended September 30, 2004		52,229			52,229
Net income (loss), three-months ended September 30, 2004	(420,915)	(27,692)	(19,737)	(22,262)	(490,606)
Net income (loss), six-months ended September 30, 2004	(974,961)	105,559	(5,405)	98,842	(775,965)
Long-lived assets At September 30, 2004	312,561	772,340	14,954		1,099,855
<b>Fiscal 2004 (restated)</b>					
Sales to customers, three-months ended September 30, 2003		1,054,549	361,822	(241,298)	1,175,073
Sales to customers, six-months ended September 30, 2003		2,269,130	694,174	(428,642)	2,534,662
Income tax expense, three-months ended September 30, 2003		28,339			28,339
Income tax expense, six-months ended September 30, 2003		120,395			120,395
Net income (loss), three-months ended September 30, 2003	(488,893)	53,640	(92,249)	48,967	(478,535)
	(808,258)	241,378	(239,329)	(121,010)	(927,219)

Net income (loss), six-months ended September 30, 2003				
Long-lived asset At September 30, 2003s	163,047	740,196	22,628	925,871

**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 similar terminology. By their very nature, forward-looking statements are subject to known and unknown risks and uncertainties relating to our future

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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.

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.

Uroplasty does not undertake and assumes no 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 SUI and for the treatment of 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 reflux of urine from the bladder to the kidneys.

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.

Our products are sold by direct sales forces in the United Kingdom, and by a network of distributors in numerous areas outside the U.S., including Europe, Australia, Canada and South America. We are currently conducting a multi-center human clinical trial with our 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.

Our current objectives are to focus on sales and marketing activities designed to increase market penetration and sales of Macroplastique for SUI, VUR, and of PTQ Implants 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**

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.



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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 September 30, 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.

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

## **Results of Operations**

**Three-month period ended September 30, 2004 compared to three-month period ended September 30, 2003 (as restated)**

Net Sales: In the second quarter ended September 30, 2004, net sales of all products were \$1,650,724, representing a \$475,651 or 40% increase when compared to net sales of \$1,175,073 for the second quarter ended September 30, 2003. Excluding fluctuations in foreign currency exchange rates, we had a sales increase of approximately 28%. We believe the continued increase in sales is related to the impact of the sales directors and managers, and their 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 83% of total net sales, respectively, during the periods presented.

Gross Profit: Gross profit was \$1,180,552 and \$869,069 for the quarters ended September 30, 2004 and 2003, respectively, or 72% and 74% of net sales. 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) and the mix of direct sales versus sales

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through distributors (with higher margins on direct sales). 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 \$489,313 during the second quarter of fiscal 2004 to \$508,260 during the second quarter of fiscal 2005. The G&A expense increase related to increased salary costs, a \$45,000 increase in professional fees for accounting, an increase of \$16,000 in legal fees and general price increases and fluctuations in foreign currency exchange rates. This increase was offset in part by decreases of \$32,000 in consulting fees and \$40,000 of shareholders expense. The increased professional fees for accounting relate to our financial statement restatements. The decrease in both the consulting fees and the shareholders expense primarily relates to the \$82,203 of stock-based compensation expense recognized in the second quarter of fiscal 2004.

**Research and Development Expense:** Research and development ( R&D ) expenses increased \$133,708, or 30%, from \$452,008 during the second quarter of fiscal 2004 to \$585,716 during the second 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 increased 58% from \$374,938 during the second quarter of fiscal 2004 to \$590,799 during the second quarter of fiscal 2005. The increase resulted from an \$80,000 increase in personnel costs, a \$107,000 increase in travel costs and costs relating to trade-shows, conventions and congresses, general price increases, and fluctuations in foreign currency exchange rates. The increased personnel costs relate to additional sales staff 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 \$(613) and \$(3,006) for the second quarters ended September 30, 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 losses of \$4,675 and \$4,210 for the second quarters ended September 30, 2004 and 2003, respectively.

**Income Tax Expense:** Our Dutch subsidiaries recorded income tax expense (benefit) of \$(14,230) and \$28,339 for the second quarter ended September 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. 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.

**Six-month period ended September 30, 2004 compared to six-month period ended September 30, 2003 (as restated)**

**Net Sales:** During the six-months ended September 30, 2004, net sales of all products were \$3,403,220, representing an \$868,558 or 34% increase when compared to net sales of \$2,534,662 for the six months ended September 30, 2003. Excluding fluctuations in foreign currency exchange rates, we had a sales increase of approximately 24%. We believe the continued increase in sales is related to the impact of the sales directors and managers, and their 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 78% and 84% of total net sales, respectively, during the periods presented.

**Gross Profit:** Gross profit was \$2,469,490 and \$1,831,687 for the six-months ended September 30, 2004 and 2003, respectively, or 73% and 72% of net sales. 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), and the mix of direct sales versus sales through distributors (with higher gross margins on direct sales). 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 \$956,542 during the six-months ended September 30, 2003 to \$899,372 during the same period of fiscal 2005. The G&A expense decrease related to \$58,000 in reduced consulting fees and \$107,000 of reduced shareholders expense, offset in part by an increase in salary costs of \$27,000, an \$84,000 increase in professional fees for accounting, 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

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\$164,407 in stock-based compensation expense recognized in fiscal 2004. The increased professional fees for accounting relate to extra work regarding the necessary restatements done and tax advisory work.

**Research and Development Expense:** Research and development ( R&D ) expenses increased \$283,805, or 32%, from \$881,964 during the six months ended September 30, 2003 to \$1,165,769 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 40% from \$799,303 during the six months ended September 30, 2003 to \$1,118,756 for the same period of fiscal 2005. This increase resulted from a \$185,000 increase in personnel costs, an additional \$175,000 in travel costs and costs relating to trade-shows, conventions and congresses, general price increases, and fluctuations in foreign currency exchange rates. The increase was offset by a \$59,000 decrease in promotional costs. The increased personnel costs relate to additional sales staff 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 \$(9,329) and \$(702) for the six months ended September 30, 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 losses of \$14,086 and \$6,571 for the periods presented.

**Income Tax Expense:** Our Dutch subsidiaries recorded income tax expense of \$52,229 and \$120,395 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.

## **Liquidity and Capital Resources**

As of September 30, 2004, our cash and cash equivalent balances totaled \$2,067,906.

At September 30, 2004, we had working capital of approximately \$3.1 million. During the six month period ended September 30, 2004, we used \$742,844 of cash in operating activities, compared to \$325,758 of cash used in the prior-year. The usage of cash was primarily attributable to the net loss incurred of \$775,965. 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 \$164,407 of non-cash stock-based compensation expense during the six months ended September 30, 2003.

Uroplasty 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 our accounts receivable and inventory balances at September 30, 2004 of \$1,136,533 and \$519,018, 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 premarket approval in the United States of our Macroplastique product. In September 2004, we signed a manufacturing and distribution agreement with CL Medical SAS, under which we have the exclusive U.S. distribution and manufacturing rights for CL Medical's product for treating SUI, which is currently sold in Europe under the brand name I-Stop. As part of that agreement, we are responsible for obtaining FDA approval of the I-Stop product. As a result, we expect to incur additional quality assurance and regulatory costs related to obtaining 510(K) approval of the I-Stop product. For the remainder of fiscal 2005, we have

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budgeted approximately \$1,400,000 for our regulatory expenses. In addition, 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.

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 R&D activities associated with existing products and markets, through fiscal 2005. Ultimately, we will need to achieve profitability and positive cash flows from operations or obtain additional debt or equity financing to fund our operations.

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

	<b>Total</b>	<b>Payments Due by Period</b>		<b>Fiscal 2007 and Thereafter</b>
		<b>Remainder of Fiscal 2005</b>	<b>Fiscal 2006</b>	
Minimum royalty payments	\$ 378,500	27,000	104,000	247,500
Notes payable	505,805	21,358	42,712	441,735
Operating lease commitments	534,533	198,986	241,752	93,795
<b>Total contractual obligations</b>	<b>\$1,418,838</b>	<b>247,344</b>	<b>388,464</b>	<b>783,030</b>

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.

**ITEM 3. CONTROLS AND PROCEDURES.**

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

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



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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 September 30, 2004.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

On September 8, 2004, we held our annual meeting of stockholders. At the meeting, our stockholders re-elected Messrs. Pitlor and Jamison to serve until our 2007 annual meeting of stockholders. The voting on their election was as follows:

For Mr. Pitlor:

Votes Cast in Favor: 3,640,313

Votes Cast Against: 2,404

Abstentions and Broker Non-Votes: 1,017,148

For Mr. Jamison:

Votes Cast in Favor: 3,640,313

Votes Cast Against: 2,404

Abstentions and Broker Non-Votes: 1,017,148

The Directors whose terms continued after the meeting are Daniel G. Holman, Sam B. Humphries and R. Patrick Maxwell.

**ITEM 5. OTHER INFORMATION.**

On September 2, 2004, we entered into a Manufacturing and Distribution Agreement with CL Medical SAS, pursuant to which we plan to distribute in the United States, on an exclusive basis, CL Medical's tension-free vaginal tape for the treatment of female SUI currently marketed in Europe under the brand name I-Stop. We have agreed to purchase our entire requirements of product components from CL Medical. We are responsible for U.S. FDA clinical and regulatory requirements for the product. The agreement is for six years, with our option to renew the agreement for successive five-year terms upon notice to CL Medical. We are responsible to purchase particular minimum amounts of product components from CL Medical during the first five years of the agreement.

**ITEM 6. EXHIBITS.**

(a) Exhibits

10.19 Form of Manufacturing and Distribution Agreement with CL Medical SAS

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

32.1 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 )

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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: November 12, 2004

by:/s/ DANIEL G. HOLMAN

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

Date: November 12, 2004

by:/s/ ARIE J. KOOLE

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Arie J. Koole  
Controller (Principal Accounting Officer)

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