UROPLASTY INC
Form 10KSB
June 28, 2002

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

FORM 10-KSB

Annual Report Pursuant To Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Fiscal Year Ended March 31, 2002

Commission File No. 000-20989

UROPLASTY, INC.
(Name of Small Business Issuer in its Charter)

Minnesota, U.S.A.	**41-1719250**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

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

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

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

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

YES [X] NO [ ]

Check if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of Company s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB. [X]

Issuer s revenues for its most recent fiscal year: $4,973,976

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 May 13, 2002 was $4,094,664.

The number of shares outstanding of the issuer s only class of common stock on May 13, 2002 was 2,047,332.

Documents Incorporated By Reference: Portions of the Company s Proxy Statement for its 2002 Annual Meeting of Shareholders (the Proxy Statement), are incorporated by reference in Part III.

Transitional Small Business Disclosure Format:

YES [ ] NO [X]

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PART I

Uroplasty, Inc. (Uroplasty , or the Company) 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 Company 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 Company s Securities and Exchange Commission filings.

Forward-looking statements may be contained in the Management s Discussion and Analysis or Plan of Operation and other section of this filing. 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 Factors Affecting the Business section of this filing.

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.

ITEM 1. DESCRIPTION OF BUSINESS

Overview

The Company designs, develops, manufactures, and markets medical products primarily for the treatment of urinary incontinence and vesicoureteral reflux. The Company s key product is Macroplastique® Implants, an injectable, soft tissue-bulking agent used to treat stress urinary incontinence (SUI), the most common form of urinary incontinence. SUI refers to the involuntary loss of urine as a result of activities that increase intra-abdominal pressure, such as coughing, laughing, or exercising. Macroplastique is also used to treat vesicoureteral reflux (VUR), a condition occurring mostly in children in which urine flows backward from the bladder into the kidney. Additionally, men recovered from prostate surgery who experience incontinence are also candidates for Macroplastique treatment. Macroplastique is CE marked in Europe (similar to FDA approval in the United States), allowing the product to be sold throughout the European Union, and is marketed in other major markets throughout the world, including Canada, Australia, and many Latin American and Pacific Rim countries. Macroplastique is not sold in the United States because it is not approved by the Food and Drug Administration (FDA) for marketing in the United States. However, the Company is currently conducting human clinical trials in the United States on Macroplastique for the treatment of female SUI pursuant to an Investigational Device Exemption (IDE).

Macroplastique® Implants

Macroplastique is an injectable soft tissue-bulking agent used to treat SUI and VUR. Macroplastique is a proprietary composition of heat vulcanized, highly textured, solid, soft, irregularly shaped polydimethylsiloxane (solid silicone) implants suspended in a biocompatible carrier solution. Based on the Company s clinical experience outside the United States, Macroplastique does not cause an adverse tissue response, and is not resorbed by the body. Macroplastique is used to provide bulking of the urethral sphincter to treat SUI in female patients. The implantation of Macroplastique is minimally invasive and can be performed in less than 30 minutes in an inpatient or outpatient setting. It is designed to restore the patient to normal urinary continence almost immediately following treatment. Macroplastique is also used to treat vesicoureteral reflux, a condition occurring primarily in children, as well as incontinence in men after prostate surgery.

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The Company markets Macroplastique through Uroplasty BV, The Netherlands, on the basis its use can lead to lower surgical risk, provide a long-lasting treatment with shorter recovery time, and is less expensive when compared to invasive alternatives. The Company believes the advantages of Macroplastique are its biocompatibility, nonabsorbancy, cost effectiveness, and its successful use in patients outside the United States since 1991.

Urinary Incontinence and Vesicoureteral Reflux Markets

Urinary incontinence is an involuntary loss of urine, which has emotional, social, and hygienic consequences. In varying degrees, urinary incontinence is a problem suffered by millions of people worldwide. The Agency for Health Policy and Research (AHCPR), a division of the Public Health Service, U.S. Department of Health and Human Services, estimates that urinary incontinence affects about 13 million people in the United States of which, 85% or 11 million are women. The same agency estimates the total cost (utilizing all management and curative approaches) of treating incontinence of all types in the United States as $15 billion. Bulking agents such as Macroplastique are used to treat women with SUI caused by intrinsic sphincter deficiency (ISD), and the National Association For Incontinence (NAFC) estimates that up to 15% of woman suffering with stress urinary incontinence is a result of intrinsic sphincter deficiency. Urethral Bulking Agents (UBA) are currently recommended by AHCPR as first-line treatment for woman with ISD who do not have coexisting urethral hypermobility. Male patients can benefit from a urethral bulking agent procedure such as Macroplastique, and according to the Agency for Health Policy and Research UBA is recommended as first-line surgical treatment for men with ISD. According to the American College of Surgeons, there are approximately 400,000 prostate surgeries performed each year in the United States, and up to 20% of these men develop incontinence following the procedure. Urinary incontinence can result in a substantial decrease in a person s quality of life, and is often the main reason a family moves an elderly person to nursing home care. The Company expects the incidence of urinary incontinence will rise as the percentage of elderly people continues to increase.

The Agency for Healthcare Research and Quality (AHRQ) reported that VUR is primarily a pediatric concern, with a prevalence estimated to be as high as 3% of the U.S. pediatric population. Approximately 15,000 surgical procedures are performed per year to address this VUR issue. Patients with VUR grades 1 through 4 in this population are candidates for Macroplastique treatments. Globally, the use of Macroplastique to correct the VUR condition can save patient costs related to continued use of antibiotics for treating these patients for chronic urinary tracts infections, which can lead to more serious related health complications.

Types of Urinary Incontinence

The mechanisms of urinary incontinence are complicated and involve the interaction between several anatomical structures. In females, urinary continence is controlled primarily by the sphincter muscle. This muscle surrounds the urethra and provides constrictive pressure to prevent urine from flowing out of the bladder. Urination occurs when the sphincter relaxes as the bladder contracts, allowing urine to flow through the urethra. The urinary sphincter is also responsible for maintaining continence during periods of physical stress. Incontinence may result when any part of the urinary tract fails to function as intended. A broad range of conditions and disorders can cause incontinence, including birth defects (e.g., Spina Bifida), pelvic surgery, injuries to the pelvic region or the spinal cord, neurological diseases (e.g. Multiple Sclerosis, Poliomyelitis), and degenerative changes associated with aging.

Stress Urinary Incontinence: SUI refers to the involuntary loss of urine due to an increase in intra-abdominal pressure from coughing, sneezing, laughing, straining or lifting. In women, the most common cause of SUI is hypermobility, a lack of anatomic stability primarily caused by weak surrounding tissue, resulting in the abnormal movement of the bladder neck and urethra. This anatomical problem is often the result of childbirth. SUI can also be caused by ISD, or the inability of the sphincter valve or muscle to function properly. ISD can be due to congenital sphincter weakness or deterioration of the muscular wall of the urethra after trauma, spinal cord lesion or radiation therapy. To date, Macroplastique has been used to treat incontinence in women suffering from SUI caused by intrinsic sphincter deficiency.

Urge Incontinence: Urge incontinence refers to the involuntary loss of urine associated with an abrupt, strong desire to urinate. Urge incontinence often occurs with neurologic problems, causing the bladder to contract and empty with little or no warning.

Overflow Incontinence: Overflow incontinence is associated with an over-distention of the bladder. This can be the result of an underactive bladder or an obstruction in the bladder or urethra.

Mixed Incontinence: Mixed incontinence is the combination of urge and stress incontinence (and, in some cases, overflow). Since prostate enlargement often obstructs the urethra, older men often have urge incontinence coupled with overflow incontinence.

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Management and Treatment of Urinary Incontinence

There are two general approaches to dealing with urinary incontinence. One approach is to manage symptoms with items such as pads or diapers. The other approach is to undergo curative treatments in an attempt to restore continence, such as injection of urethral bulking agents or by invasive surgeries. The Company believes and endorses the treatment of urinary incontinence from the least invasive to the most invasive therapy as needed.

Management of Urinary Incontinence

Absorbent Products: Absorbent products are the most common form of management for urinary incontinence because men and women can use them without consulting a physician. The cost of adult diapers and pads can be substantial, thus creating a continuous financial burden for patients. Additionally, this management technique may require frequent changing of diapers and pads to control patient embarrassment due to odor and/or soiling.

Behavior Modification: The techniques used in behavior modification include bladder training, scheduled voiding, and pelvic floor muscle exercises known as Kegels. Some of the tools used in conjunction with these training regimes are vaginal cones or weights, biofeedback devices, and electrical stimulation. Although these techniques are not effective in all patients, the company believes that biofeedback or one of the other behavior modifications should be used as a first line of treatment.

Penile Compression Devices: Penile clamps are reserved for temporary use with male incontinence. Complications such as penile and urethral erosion, penile edema, pain, and obstruction can be associated with extended and/or improper use.

Pelvic Organ Support Devices: A pessary is a doughnut-shaped device made of flexible materials. They are designed to temporarily reduce pelvic prolapse and alleviate symptoms of pelvic relaxation in females with and without incontinence. When these devices are misused or neglected, complications such as ulceration of the vagina and rectovaginal and vesicovaginal fistula can occur. Persons using pessaries require frequent, regular monitoring.

Occlusion Devices: Urethral occlusion devices, or plugs , of various designs are temporarily applied to occlude the urethra and/or bladder. They are disposable products and either fit over the urethral opening or in the urethra and/or bladder to obstruct the involuntary leakage of urine. The primary problems with these devices are urinary tract infections, treatment compliance, and progressive urethral dilation that may require larger plugs over time.

Urinary Catheters and Collection Devices: There are four types of urinary catheters: 1) intermittent (inserted through the urethra into the bladder every 3 to 6 hours for bladder drainage; may be appropriate for the management of acute or chronic urinary retention); 2) indwelling (a closed sterile system inserted through the urethra to allow bladder drainage; may be needed for short-term treatment and for terminally ill patients); 3) suprapubic (requires percutaneous or surgical introduction of a catheter into the bladder through the abdominal wall, for short-term use following gynecologic, urologic and other types of surgery or as an alternative to long-term urethral catheter use in men); and 4) external collection (devices made from latex rubber, polyvinyl or silicone resembling a condom, are secured on the shaft of the penis by a double-sided adhesive, latex or foam strap and are connected to urine collecting bags by a tube; may be useful for short-term maintenance). The type and severity of incontinence and the patient s physical and mental condition determine which is the best catheter option for the patient.

Drug Therapy: Drug treatment is used to manage multiple types of urinary incontinence. These drugs tend to fall into one of two categories: those that manage urge urinary incontinence by affecting the contraction of the muscle tissue of the bladder, and those that manage stress urinary incontinence by either affecting contraction of the muscle tissue of the bladder neck or improving the quality of the mucosal lining of the bladder neck and urethra. Drugs seldom cure stress urinary incontinence and the potential side effects include urinary retention, nausea, dizziness, blurred vision, and the possibility of unwanted interactions with other drugs.

Curative Treatments for Urinary Incontinence

Surgery: In women, SUI can be surgically corrected through various suspension and sling procedures. In these procedures, the physician elevates and stabilizes the urethra and bladder neck. Current surgical procedures require vaginal or abdominal incisions and are typically performed under general anesthesia. Surgery is expensive, traumatic, and can involve a hospital stay with several weeks required for full recovery. In men, the main surgical option is an implanted artificial urinary sphincter. It carries with it the inherent risks of device malfunction, tissue erosion and atrophy, and infection. In practice, the artificial urinary sphincter is rarely applicable to the management of uncomplicated stress incontinence.

Injectable Bulking Agents: Urethral Bulking Agents (UAB)s are inserted with a needle into the area around the urethra, thereby augmenting or bulking the sphincter. Hence, these materials are often called bulk-enhancing agents , bulking

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agents , or injectables . Urethral bulking agents may be either synthetic or biologically derived and are an attractive alternative to surgery because they are considerably less invasive than many of the surgical procedures described above. For this reason, bulking agents represent a particularly desirable treatment option for the elderly or infirm who may not otherwise be able to withstand the trauma and morbidity resulting from a fully invasive surgical procedure. Active women benefit from the use of urethral bulking agents since their use will often allow the patient to return to normal activities in a matter of days instead of weeks for fully invasive surgical procedures. Additionally, the use of a UBA does not preclude the use of more invasive treatments later on if the need arises. The Clinical Practice Guidelines published by the U.S. Department of Health and Human Services recommend periurethral bulking agents as a first line treatment for men with ISD and for women with ISD who do not have co-existing hypermobility. Bulking agents should be positioned as a primary minimally invasive procedure to treat only Type I, Type IIb, and Type III patients without major prolapse or hypermobility component. Slings or suspensions should be positioned to treat patients with major prolapse or hypermobility.

The two major types of urethral bulking agents are biologically derived and synthetic agents. Biologically derived bulking agents include injections of a patient s own fat cells, polysaccharides (not commercially available in the U.S.) or bovine collagen. Fat injections involve complex, invasive harvesting of the patient s own fat cells and reinjecting them into the bladder neck. Some of these biological agents require pre-treatment allergy tests, and since the body resorbs these agents over time, subsequent reinjections may be necessary. Macroplastique (polydimethylsiloxane) is a synthetic silicone elastomer bulking agent. Although physicians and patients may question the silicone issue, we are confident that we provide support and documentation to show the difference between our silicone elastomer product and the silicone gel products that were associated with the breast implants. Other synthetic bulking agents are composed of polytetrafluoroethylene (PTFE) (not commercially available in the U.S.) and pyrolytic carbon-coated beads.

Marketing, Distribution, and Sales

The Company markets and sells Macroplastique and the related ancillary products used in the implantation procedure only in countries outside the United States. The Company has a direct sales forces consisting of four persons in the United Kingdom. Additionally, the Company employs two sales managers in The Netherlands and one in the United States to manage a network of distributors selling the Company s products outside the United States in approximately 40 countries including Canada, Australia, and countries within Europe, Latin America and the Pacific Rim. The Company s technical staff in The Netherlands and the United States trains both new as well as existing distributors. The Company has written territory-specific distribution agreements with each of the individual distributors. None of the distributors may sell injectable products that compete directly with Macroplastique. During fiscal 2002, approximately 12% of the Company s net sales were to one customer. During fiscal 2001 no customer exceeded 10% of the Company s net sales. Collectively, the Company s distributors accounted for approximately 63% and 58% of total net sales in fiscal years 2002 and 2001, respectively.

The Company markets a patented, non-endoscopic delivery kit called the Macroplastique Implantation System (MIS) for treatment of female stress urinary incontinence outside the United States. The MIS is for use by urologists, gynecologists, and urogynecologists for the implantation of Macroplastique without the aid of an endoscope. Historically, urologists have principally performed the Macroplastique procedure, however the Company believes with the MIS, Macroplastique will be available to a larger number of physicians (specifically gynecologists) and therefore will be available to more female SUI sufferers. There can be no assurance the MIS will have any significant effect on increasing sales of Macroplastique.

Other Products

In addition to the urological applications, the Company s implantable bulking material is also marketed outside the United States for reconstructive and cosmetic plastic surgery, and otolaryngology vocal cord rehabilitation applications under the trade name Bioplastique Implants. In The Netherlands and United Kingdom only, the Company s direct sales force distributes certain wound care products in accordance with a distributor agreement. Under the terms of the Distributor Agreement, the Company is not obligated to purchase any minimum level of wound care products. Collectively, these other products accounted for 11% and 8% respectively, of the Company s net sales in fiscal 2002 and fiscal 2001.

Government Regulations

The Company s medical device products are subject to regulation by various governmental agencies depending upon where the products are manufactured and/or sold. In markets such as the United States and Europe, these regulations are substantial and can significantly affect a company s ability to obtain and/or maintain approval for manufacturing and distribution of medical device products.

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In order to market its products within the countries consisting of the European Union, the Company is required to obtain CE marking for its products. To obtain CE marking, a product must comply with the requirements set forth in Council Directive 93/42/EEC published in Volume 36 (12 July 1993) of the Official Journal of the European Communities, referred to as the Medical Device Directives (MDD). CE mark authorization is granted by organizations called Notified Bodies who are approved by their respective national Competent Authorities (sometimes referred to as National Health Ministries) to conduct medical device evaluations. Notified Bodies are technical experts serving as the auditing and certifying arm of the Competent Authorities.

Under the European MDD, Macroplastique is considered a Class IIb long-term implantable device. To obtain the CE mark for Macroplastique, the Company was required to submit extensive information regarding product design, labeling, and preclinical and clinical safety testing to its Notified Body for evaluation by expert reviewers. In addition, the Company maintains registration to rigorous quality standards ISO 9001, ISO 13485 and EN 46001. After successfully demonstrating full compliance to the MDD, the Notified Body issued a Certificate of Authorization to the Company in June 1996, allowing the Company to place the CE mark on Macroplastique and Bioplastique and their related accessories. From 1991 to 1996, the Company marketed products in Europe through individual country registrations. By complying with the MDD and any specific National requirements, Macroplastique is marketed throughout the European Union. The Company is subject to periodic surveillance audits by its Notified Body to ensure it adheres to the requirements of the MDD, as well as quality standards ISO 9001, ISO 13485 and EN 46001. Changes in existing requirements or adoption of new requirements or policies could adversely affect the ability of the Company to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on the Company s business, financial condition, and results of operations. There can be no assurance the Company will not be required to incur significant costs to comply with laws and regulations in the future, or that laws or regulations will not have a material adverse effect upon the Company s business, financial condition, or results of operations.

The Company maintains facilities in the United States, United Kingdom, and The Netherlands, each of which has numerous federal, state, and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. To the best of our knowledge, the Company complies with all applicable local, state and national laws. There can be no assurance the Company will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect upon the Company s ability to do business, financial condition, or results of operations.

The Company is structured so that The Netherlands subsidiary conducts business as a manufacturer and international sales office, and is responsible for the worldwide distribution of Macroplastique products outside of the United States through our network of independent distributors. The United Kingdom subsidiary is responsible for direct sales and distribution of Macroplastique products to hospitals and physicians within the United Kingdom and Ireland. As a result of our corporate structure, the U.S. regulation regarding medical exports that are not FDA approved does not materially affect our business. In the United States, the Company must comply with the Federal Food, Drug, and Cosmetic Act, as amended, which is enforced by the FDA. The FDA has determined urethral bulking agents such as Macroplastique are Class III devices subject to a Pre-Market Approval (PMA) application prior to marketing in the United States.

A PMA is a rigorous submission requiring the manufacturer to substantiate claims of safety and effectiveness with valid scientific evidence. The PMA process is lengthy and expensive with no guarantee of final approval at its completion. In some instances, the FDA may decide additional testing or clinical studies are necessary to support the PMA submission. Such a decision considerably lengthens the time and expense required for obtaining U.S. marketing approval. If the FDA approves the PMA submission, it may still place certain conditions on the manufacturer such as the initiation of a post-marketing study or restrictions to the product s intended use.

After PMA approval, the Company must comply with FDA regulations to maintain its U.S. marketing approval. The Company s manufacturing facilities will be subject to routine inspections by the FDA to ensure compliance with U.S. Quality System Requirements. Even though the Company has achieved ISO 9001, ISO 13485 and EN 46001 registrations, there can be no assurance the FDA would find the Company s quality system to be in compliance with all relevant aspects of the U.S. requirements. The Company is also subject to a variety of state and local laws and regulations in those states or localities where its product will be manufactured and/or marketed. Any applicable state or local regulations may hinder the Company s ability to market its products in those states or localities.

Third-Party Reimbursement

Reimbursement systems vary significantly by country. Third-party payors consist of government health programs, private health insurance plans, managed care organizations and other similar programs. Outside of the United States, government managed health care systems control reimbursement for devices and procedures such as Macroplastique. Reimbursement for Macroplastique has been successful in multiple international markets where hospitals and physicians have been able to get budgets approved by fund-holder trusts or global hospital budgets. Physicians or hospitals that apply, but do not

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receive satisfactory reimbursement from either third-party payors or the government, may choose not to use Macroplastique, and the sales of our products could be affected. Upon FDA approval to market Macroplastique in the United States, Uroplasty will need to apply for and gain acceptance from Medicare and other third-party reimbursement. There is no uniform policy for reimbursement throughout the United States, and no guarantee Macroplastique will be reimbursed at the levels expected by the Company, if at all.

Product Liability

The medical device industry is subject to substantial litigation. The Company is a manufacturer of a long-term implantable device and consequently faces an inherent business risk of exposure to product liability claims resulting from alleged adverse effects to the patient. The Company currently carries $2 million of worldwide product liability insurance on a claims made form, plus another policy specific to the United Kingdom only. There can be no assurance, however, the Company s existing insurance coverage limits are adequate to protect the Company from any liabilities it might incur in connection with the clinical trials of Macroplastique or the initial commercialization of Macroplastique in the United States. There can be no assurance that liability claims will not exceed coverage limits. Such insurance is expensive and in the future may not be available on acceptable terms, if at all. Furthermore, the Company does not expect to be able to obtain insurance covering its costs and losses as a result of any recall of its products due to alleged defects, whether such a recall is instituted by the Company or required by a regulatory agency. A product liability claim, recall, or other claim with respect to uninsured liabilities or in excess of insured liabilities could have a material adverse effect on the business, financial condition, and results of operations of the Company.

Manufacturing

The Company manufactures Macroplastique at its own facilities. Components are manufactured in the United States, and finished products are manufactured in The Netherlands from medical grade materials obtained from suppliers qualified by the Company s Quality Department. The Company s facilities utilize dedicated heating, ventilation, and high efficiency particulate air (HEPA) filtration systems for the manufacturing areas to provide a controlled working environment. All manufacturing processes are performed by trained production technicians according to written procedures approved by the Company s Quality Department. All critical manufacturing processes are performed in a cleanroom environment. An outside vendor sterilizes Macroplastique, Bioplastique and their accessories using validated methods and returns the products to the Company for final inspection and testing.

The Company s manufacturing facilities are periodically audited by an independent registrar to ensure compliance with ISO 9001 ISO 13485 and EN 46001 quality system requirements. Prior to marketing the product in the United States, the Company will also be inspected by the U.S. FDA and will be subject to additional state, local, and federal government regulations applicable to the manufacture of the Company s products. See Description of Business Government Regulations .

Competition

Competition in the urinary incontinence products market is intense. The Company faces competition from existing manufacturers of management and curative treatments, competing manufacturers of commercially available bulking agents, and from companies developing new or improved treatment methods. The Company believes the principal competitive factors among treatment methods include physician and patient acceptance of the method in managing or curing incontinence, cost and availability of third-party reimbursement, marketing and sales capability, and the existence of meaningful patent protection. The Company s ability to compete in this market also will depend on the consistency of its product quality as well as delivery and product pricing. Other factors within and outside the Company s control include its product development and innovation capabilities, ability to obtain required regulatory approvals, ability to protect its proprietary technology, manufacturing and marketing capabilities, and ability to attract and retain skilled employees.

Other soft-tissue injectable urethral bulking agents competing directly with Macroplastique for the treatment of stress urinary incontinence and/or vesicoureteral reflux are Contigen® manufactured by C.R. Bard, Inc., Zuidex® and Deflux® manufactured by Q-Med AB, and Durasphere® manufactured by Carbon Medical Technologies, which is marketed in the U.S. by Boston Scientific. In addition, the Company believes Curis, Inc., Protein Polymer Technologies, Genyx Medical, and Bioform, Inc. are performing research and development and/or are seeking regulatory approval for various types of soft-tissue injectable bulking agents for treatment of urinary incontinence. In contrast to the products currently approved for sale, Macroplastique, marketed outside the United States since 1991, is a synthetic material that will not degrade, become resorbed or migrate, and does not require the patient to have a skin test prior to the procedure. The silicone-elastomer material has been studied for over 50 years in medical use for such urological applications as penile implants, stents and catheters. The patented Macroplastique Implantation System (MIS) offers a unique, non-endoscopic, minimally invasive delivery system that can be performed in the physician office as an out-patient procedure. The

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Company expects continued stiff competition with Johnson & Johnson, American Medical Systems, C.R. Bard Inc., Cook Urological, Boston Scientific Corporation and others who manufacture urinary incontinence surgical products such as sling devices. These companies have the advantage to bundle their incontinence products or devices onto contracts that require a hospital to purchase the incontinence device in order to maintain discounts on other product lines.

Many of the Company s competitors and potential competitors have significantly greater financial, manufacturing, marketing, distribution and technical resources, and experience than the Company. In addition, many of the Company s competitors offer broader product lines within the urology market, which may give such competitors the ability to negotiate exclusive, long-term supply contracts and to offer comprehensive pricing for their products. It is possible other large health care and consumer products companies may enter this industry in the future. Furthermore, smaller companies, academic institutions, governmental agencies, and other public and private research organizations will continue to conduct research, seek patent protection, and establish arrangements for commercializing products. Such products may compete directly with any products, which may be offered by the Company in the future.

Dependence on One or a Few Major Customers

During fiscal 2002, approximately 12% of the Company s net sales were to one customer. During fiscal 2001, no customer exceeded 10% of the Company s net sales.

Patents, Trademarks, and Licenses

The Company s success depends in part on its ability to obtain and maintain patent protection for its products, preserve its trade secrets, and operate without infringing the proprietary rights of third parties. The Company seeks to protect its technology by filing patent applications for patentable technologies it considers important to the development of its business based on an analysis of the cost of obtaining a patent, the likely scope of protection, and the relative benefits of patent protection compared to trade secret protection, among other considerations. The Company also relies upon trade secrets, know-how, and continuing technological innovation to develop and maintain its competitive position.

Multiple patents covering the Macroplastique materials, processes, and applications have been issued to the Company by the Patent Offices in the United States, United Kingdom, Japan, Germany, The Netherlands, and Canada. Such patents will expire in the U.S. at various times between 2010 and 2013. Applications are also currently pending in various other European countries. There can be no assurance any of the Company s pending and/or future U.S. and/or foreign patent applications will result in issued patents, or that any issued patents will be of sufficient scope or strength to provide meaningful protection of the Company s products. The coverage sought in a patent application can be denied or significantly reduced before the patent is issued. In addition, there can be no assurance any current and/or future U.S. and/or foreign patents of the Company will not be challenged or circumvented by competitors or others, or that such patents will be found to be valid or sufficiently broad to protect the Company s technology or provide the Company with any competitive advantage. Should attempts be made to challenge, circumvent, or invalidate the Company s patents in the U.S. Patent and Trademark Office or courts of competent jurisdiction, including administrative boards or tribunals, the Company may have to participate in legal or quasi-legal proceedings therein to maintain, defend, and/or enforce its rights in these patents. Any legal proceedings to maintain, defend, and/or enforce the Company s patent rights could be lengthy and costly, with no guarantee of success.

The Company also relies heavily upon trade secrets and other proprietary information. The Company seeks to maintain the confidentiality of such information by requiring employees, consultants, and other parties to sign confidentiality agreements, and by limiting access by parties outside the Company to such information. There can be no assurance, however, these measures will prevent the unauthorized disclosure or use of this information or that others will not be able to independently develop such information. Additionally, there can be no assurance any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to the Company.

In July 21, 1998, the Company announced the United States Patent and Trademark Office (USPTO) had informed the Company the USPTO would, as requested by the Company, initiate an interference proceeding (the Interference Proceeding) between the Company and Carbon Medical Technologies, Inc. (CMT), formerly Advanced UroScience, Inc., White Bear Lake, Minnesota, to determine which company was the first to invent pyrolytic carbon-coated micro beads for use in treating urinary incontinence.

Later in 1998, the Company commenced a related lawsuit against CMT for misappropriation of trade secrets (Misappropriation Lawsuit) pertaining to the pyrolytic carbon-coated micro beads, among other things and CMT subsequently brought a counterclaim against the Company with respect to such matter.

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Effective October 26, 2001, the Company and CMT entered into a Settlement Agreement terminating the above-referenced legal proceedings; as a part of such Agreement, the Company agreed to dismiss the Misappropriation Lawsuit and to abandon the Interference Proceeding.

Proceeds from the Settlement, totaling $407,000, will be recognized upon the receipt of cash. During the fiscal year ended March 31, 2002, the Company received and recorded a $200,000 gain related to this settlement. In the first quarter of fiscal 2003 the Company received and recorded a $207,000 gain.

In 1992, the Company and its then parent, Bioplasty, Inc., were sued by Collagen Corporation, which alleged that Macroplastique infringed on one of its U.S. patents for a bulking agent. The parties entered into a license and settlement agreement in 1993 pursuant to which the Company pays Collagen a royalty of 5% of net sales in the U.S. of Macroplastique products with a minimum of $50,000 per year. The duration of the Collagen Corporation agreement is through May 1, 2006. Collagen has not brought any new or renewed legal action in connection with its allegations. There can be no assurance, however, Collagen and/or any other third party will not pursue legal action with respect to these matters.

Claims by competitors, such as Collagen and other third parties that the Company s products allegedly infringe the patent or other intellectual property rights of others, could have a material adverse effect on the Company. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, and intellectual property litigation may be used against the Company as a means of gaining a competitive advantage. Intellectual property litigation is complex, time-consuming, and expensive, and the outcome of such litigation is difficult to predict. Any future litigation, regardless of outcome, could result in substantial expense to the Company and significant diversion of the efforts of the Company s technical and management personnel. An adverse outcome in any litigation could subject the Company to significant liabilities to third parties, require disputed rights to be licensed from others, if licenses to such rights could be obtained, or require the Company to cease making, using, or selling certain products. There can be no assurance that any licenses required under any patents or proprietary rights would be made available on terms acceptable to the Company, if at all. In addition to being costly, protracted litigation to defend or prosecute intellectual property could result in the Company being unable to commercialize Macroplastique on a timely basis or at all, and could have a material adverse effect on the Company s business, financial condition, and results of operations.

Although the Company intends to apply for additional patents and vigorously defend issued patents, management believes its success as a business will depend primarily upon its development and marketing skills, and the quality and economic value of its products rather than on its ability to obtain and defend patents.

The Company has a Royalty Agreement with three individuals, two of whom are former officers and directors. Under such Agreement, the Company pays royalties, in the aggregate, of three to five percent of net sales of Macroplastique and Bioplastique, 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.

In December 1995, the Company obtained a license from a British surgeon, which became superseded by a subsequent Agreement entered into by the parties in October 1998. Pursuant to this subsequent Agreement, the Company received an absolute assignment of a patent relating to the Macroplastique Implantation System in return for a royalty of 10 British pounds for each unit sold during the life of the patent. The Company began commercialization of the product outside the U.S. in March 2000.

Research and Development

The Company has an active Research and Development program working to develop new products in the field of incontinence. The Company is also continually evaluating potential improvements as well as new methods and devices for the implantation of Macroplastique and on new applications for this material. R&D expenses also include the costs of clinical studies including the U.S. clinical trial currently underway pursuant to the IDE approved by the FDA. Expenditures for research and development totaled $1,685,000 and $2,150,177 for the fiscal years ended March 31, 2002 and 2001, respectively. None of these costs were borne directly by customers.

Compliance with Environmental Laws

Compliance by the Company with applicable environmental requirements during its fiscal years ended March 31, 2002 and 2001 has not had a material effect upon its capital expenditures, earnings, or competitive position.

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Employees

As of March 31, 2002, the Company had 37 employees, of which 34 were full-time and 3 part-time. No employee has a collective bargaining agreement with the Company. The Company believes it maintains good relations with its employees.

Incorporation and Current Subsidiaries

The Company was incorporated in January 1992 as a Minnesota Corporation and a wholly owned subsidiary of its parent. In February 1995, the Company became a stand-alone, privately held company pursuant to a Plan of Reorganization confirmed by the U.S. Bankruptcy Court. The Company s shares became registered and the Company became a reporting company pursuant to a registration statement filed with the Securities and Exchange Commission in July 1996.

The Company s wholly owned foreign subsidiaries and their respective principal functions are as follows:

Uroplasty BV	Incorporated in The Netherlands, is the manufacturer of Macroplastique and Bioplastique and all their accessories, and sells its products through distributors.
Uroplasty LTD	Incorporated in and acts as the sole distributor of Macroplastique and wound care products in the United Kingdom.
Bioplasty BV	Incorporated in The Netherlands and is the distributor of Bioplastique to subdistributors, and distributes wound care products in The Netherlands.

Factors Affecting the Business

The following factors are important and should be considered carefully in connection with any evaluation of the Company s business, financial condition, results of operations and prospects. Additionally, any one or combination of the following factors could cause the Company s actual results to materially differ from those reflected in any forward-looking statements of the Company.

Government Regulation: The Company s product, manufacturing processes, and product development activities are subject to extensive and rigorous regulation by governmental and regulatory authorities in foreign countries similar to the U.S. Food and Drug Administration (FDA). In Europe, where Macroplastique® has been used since 1991, the Company s introduction of medical devices as well as the design, manufacturing, labeling, distribution, sale, marketing, advertising, promotion, and record keeping procedures for the Company s products are subject to laws and regulations governing medical devices contained in the European Medical Device Directives (MDD).

In the United States, the Company cannot market or sell Macroplastique until pre-market approval (PMA) authorization is received from the FDA. In July 1999, Uroplasty received approval from the FDA of an Investigational Device Exemption (IDE) relating to a U.S. clinical trial for the treatment of female stress urinary incontinence (SUI) using Macroplastique. Upon successful completion of the clinical trial, the Company plans to submit a PMA application to the FDA requesting approval to commercialize Macroplastique in the U.S. There can be no assurance the U.S. clinical trials will be successfully completed or that the requisite approvals or certifications will be granted for Macroplastique or any other product on a timely basis, or at all, or that such regulatory reviews will not involve delays that would conflict with the Company s ability to commercialize its products in the U.S.

If and when regulatory approval to market a product is obtained from the FDA, this approval may necessitate limitations on the indicated uses of the product. Marketing approval can also be withdrawn by the FDA in the United States (and by regulatory authorities in foreign countries) due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following initial approval. The Company may be required to make further filings with the FDA and other regulatory authorities in foreign countries under certain circumstances, such as the addition of product claims or product reformulation. The FDA and other regulatory authorities in foreign countries could also limit or prevent the manufacture and/or distribution of the Company s products and have the power to demand the recall of such products. Medical device regulations depend strongly on administrative interpretation, and there can be no assurance future interpretation made by the FDA or other regulatory bodies, with possible retroactive effect, will not adversely affect the Company. The FDA and various other authorities either currently inspect or will inspect the Company s facilities from time to time to determine whether Uroplasty is in compliance with regulations relating to medical device manufacturing including regulations concerning design, manufacturing, testing, quality control, product labeling, distribution, promotion, and record keeping practices. A determination that the Company is in material violation of such regulations could lead to the imposition of civil penalties, including fines, product recalls, product seizures or, in extreme cases, criminal sanctions.

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Effects of Technological Developments: The Company competes in a market characterized by technological innovation, extensive research efforts, and significant competition. Improvements in existing treatment options or developments of new treatment methods may have a material adverse effect on the Company s ability to increase sales of Macroplastique, successfully commercialize any future products, and may render such products noncompetitive or obsolete. Other companies are currently engaged in the development of products and innovative methods for treating SUI that are similar to or competing with Macroplastique and these companies may have greater financial resources and know how than the Company. Significant developments by any of these companies or advances by medical researchers could eliminate the market for Macroplastique or otherwise render Macroplastique obsolete. Although technological change has not had a direct material impact on the Company in recent years, the potential such a change might occur is a continuing risk for the Company.

Macroplastique Market Acceptance: The Company currently sells Macroplastique in Europe, Canada and other countries outside the United States. Acceptance of Macroplastique by physicians in preference to other treatment options, including other bulking agents, will depend upon the demonstration of its safety and effectiveness, relative performance of Macroplastique compared to other market approved products, availability of other treatment options, and ease of use and relative cost compared to treatment options including other bulking agents. Physicians may elect not to use Macroplastique unless adequate reimbursement from health care payers is available. Health care payer acceptance of a treatment utilizing Macroplastique will require, among other things, evidence of the cost effectiveness of this treatment as compared to other treatment options. There can be no assurance the acceptance of Macroplastique by urological and gynecological health care providers will develop or continue to grow in countries where Macroplastique is already used.

Single Product: The Company currently derives over 89% of its net sales of Macroplastique and related products. Discontinuance or reduction of revenues from Macroplastique sold outside of the U.S. could therefore have a material adverse effect on the Company s business, financial condition, and results of operations. The Company does not expect commercialization of other new products will be feasible without a substantial, continuing commitment to research and development for an extended period of time or acquisitions of new products, or both. Also, new medical products must typically undergo clinical trials and regulatory clearance or approval before commercialization. There can be no assurance as to whether or when commercialization of other products might begin or as to the likelihood that any such initiative would be successful. The market for medically-related products changes constantly. If the market changes, new or strengthened competition emerges, customer preferences change, and/or new technology causes Macroplastique to be viewed as a less effective treatment, the Company s business, financial condition, and results of operation would be adversely affected.

Patents and Proprietary Rights: The Company s success depends in part on the ability to preserve trade secrets, obtain and maintain patent protection for Uroplasty s products under United States and international patent laws and other intellectual property laws, and operate without infringing upon the proprietary rights of third parties. Patents covering the materials, process, and applications have been issued to the Company by the Patent Offices in the United States, United Kingdom, Japan, Germany, The Netherlands, and Canada. Applications are also currently pending in various other European countries. No assurances can be given that the scope of any patent protection will prevent competitors (most of which have financial and other resources substantially greater than the Company) from introducing products competitive with the Company s products, the Company s patents will be held valid if subsequently challenged, others will not claim rights in or ownership of the patents and other proprietary rights held by the Company, or the Company s product and processes will not infringe, or be alleged to infringe, the proprietary rights of others.

A number of patents have been issued to others in the area of injectable bulking agents. The validity and breadth of claims covered in medical device technology patents involve complex legal and factual questions and may therefore be highly uncertain. The Company also relies upon unpatented trade secrets to protect the Company s proprietary technology. No assurance can be given that others will not independently develop or otherwise acquire substantially equivalent techniques and/or gain access to and disclose the Company s proprietary technology. Further, no assurance can be given that the Company can ultimately protect meaningful rights to such unpatented proprietary technology. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Litigation may be necessary to enforce any patents issued to the Company, protect trade secrets or proprietary information owned by the Company against claimed infringement of the rights of others, or determine the scope and validity of the proprietary rights of others. The defense and prosecution of patent litigation or other legal and/or administrative proceedings related to patents is costly and time-consuming regardless of the outcome. An adverse outcome in any litigation could subject the Company to significant liabilities to third parties, require disputed rights to be licensed from others, and/or require the Company to cease making, using, or selling any products. There can be no assurance that any licenses required under any patents or proprietary rights would be made available on terms acceptable to the Company, if at all.

Public Reaction to Silicone Products: Macroplastique is comprised of heat-vulcanized polydimethylsiloxane, which results in a solid, flexible silicone elastomer. In the early 1990 s the United States breast implant industry became the

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subject of significant controversies surrounding the possible effects upon the human body of the use of silicone gel in breast implants resulting in a massive flood of product liability litigation, leading to the bankruptcy of several companies, including Uroplasty s former parent, Bioplasty, Inc. The Company uses only solid silicone material and not semi-liquid silicone gel (as was used in breast implants) in the Macroplastique product. However, there can be no assurance that the use by the Company and others of solid silicone in medical devices implanted in the human body will not result in controversies, litigation, or negative publicity from news media, competitors or legislative and regulatory investigations. Furthermore, there can be no assurance that in the event such negative publicity occurred, that it would not have a significant adverse effect on the Company s future financial position or results of operations.

Third-Party Reimbursement: Any success of the Company will depend, in part, upon satisfactory reimbursement for Macroplastique procedures from third-party health care payers. In the U.S. and many foreign countries, third-party reimbursement is currently generally available for surgical procedures for urinary incontinence, but there is no uniform policy for such reimbursements. The Company sells Macroplastique to physicians, hospitals and other users which bill various third-party payers, such as government health programs, private health insurance plans, managed care organizations, and other similar programs for the health care products and services provided to their patients. Payers may deny reimbursement if they determine a product used in a procedure was not used in accordance with established payer protocols regarding cost-efficient treatment methods, was used for an unapproved indication or was not otherwise covered. Third-party payers are increasingly challenging the prices charged for medical products and services and, in some instances, have pressured medical suppliers to lower their prices. The availability of third-party reimbursement for Macroplastique or competitors products and continuing efforts to reduce the costs of health care by decreasing reimbursement rates may reduce the price received by the Company for Macroplastique or increase the relative expense to the consumer. The Company believes a material amount of Macroplastique revenues are received from third-party payers; therefore failure to receive sufficient reimbursement from health care payers for procedures using Macroplastique or adverse changes in governmental and third-party payers policies toward reimbursement for such procedures would materially adversely affect the Company s business, financial condition, and results of operations.

Clinical Studies: There are numerous abstracts and articles that support Macroplastique for the treatment of SUI and VUR published in the scientific literature. The majority of these publications are uncontrolled, which preclude their use in obtaining marketing clearance in the United States. Consequently, the Company is currently conducting a human clinical trial pursuant to an IDE approval by the FDA that will provide a controlled, prospective clinical study concerning Macroplastique treatment for female SUI. Until this study is completed, no assurance can be given that Macroplastique will receive marketing clearance in the United States.

Raw Material / Component Suppliers: The Company currently purchases certain materials from single, qualified and approved sources. Alternative suppliers for all these materials exist should the current suppliers discontinue production or distribution. However, the Company would need to complete additional testing to qualify the materials obtained from any new suppliers. Limited notice of the need to switch suppliers for any of these materials could result in production delays and inventory depletion, and alternative suppliers could change prices significantly higher than current costs. The Company has not experienced any shortage of these materials to date; however, no assurance can be given that shortages of these materials will not be experienced in the future.

Research and Development Expenses and Expected Losses: The Company s future success will depend upon, among other factors, its ability to introduce and market Macroplastique on a timely basis in the U.S. and, to that end, the Company has committed the largest portion of the proceeds resulting from its private placement of Common Stock in fiscal 1998. Although the Company realized net income during fiscal years 1997 through 1999, the Company incurred substantial losses in fiscal 2000, fiscal 2001 and fiscal 2002. The development and commercialization by the Company of Macroplastique and other products in the U.S. will require substantial additional product development, clinical, regulatory, and other expenditures for the foreseeable future.

Additional Capital Requirements: In the event product sales and/or expenses differ from expected levels, the Company may require additional financing to complete the IDE clinical study and pre-market approval application for Macroplastique in the U.S. Further, the Company will need additional funds for market introduction of Macroplastique to the U.S. for female SUI, as well as for the development of VUR and male incontinence markets, because separate regulatory approval is needed for each of these indications. As of record date May 13, 2002, the Company is offering a total of 3,071,535 shares and 1,023,845 warrants to each of its shareholders, each of whom holds one subscription right for each two shares of common stock held on such date. If all of the rights are sold, the Company will receive gross proceeds of $3.1 million. There is no assurance that this offering will be partially or fully completed.

International Operations and Currency Fluctuations: The Company currently sells its products only outside the U.S. through its wholly owned foreign subsidiaries. Sales and operations outside of the U.S. are subject to certain inherent risks, including, without limitation, fluctuations in the value of the U.S. dollar relative to foreign currencies, tariffs, quotas, taxes and other market barriers, political and economic instability, restrictions on the import and export of technology, difficulties in staffing and managing international operations, difficulties in obtaining work permits for

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employees, difficulties in collecting receivables, potentially adverse tax consequences, potential language barriers, and difficulties in operating in a different culture and legal system. There can be no assurance that any of these factors will not have a materially adverse effect on the Company s financial condition or results of operations. In particular, because the Company s international sales are denominated primarily in Euros, currency fluctuations in countries where the Company does business may render the Company s products less price competitive than those of competing companies whose sales are denominated in weaker currencies. The Company reports its financial results in U.S. dollars, and fluctuations in the value of either the dollar or the currencies in which the Company transacts business can have a negative impact on its financial condition or results of operations. Consequently, the Company has exposure to foreign currency exchange risks. The Company attempts to lessen that exposure by keeping to a minimum the amount of time trade payables and receivables are outstanding, and by denominating product sales in a currency which historically has been more stable than other foreign currencies. However, there can be no assurance that historical stability of any currency is any indication of its future stability.

Limited Public Market for Common Stock; Possible Stock Price Volatility: Announcements of new products and services by the Company or its competitors, technological innovations by competitors, disputes regarding patents or other proprietary rights, regulatory developments and economic and other external factors, as well as period-to-period fluctuations in the Company s financial results, could cause the market price of the Company s Common Stock to fluctuate significantly. In addition, the stock market in general and, in particular the market prices for medical technology companies, have historically experienced significant volatility which has affected the market price of securities of many companies and which has sometimes been unrelated to the operating performance of such companies. Such volatility may adversely affect the market price of the Company s Common Stock.

ITEM 2. DESCRIPTION OF PROPERTY

The Company owns office and warehouse space at Hofkamp 2, 6161 DC Geleen, The Netherlands. In addition, the Company leases office, warehouse, laboratory and production space through February 2003 at 2718 Summer Street NE, Minneapolis Minnesota 55413-2820, USA; office and warehouse space through September 2011 (subject to a right of the Company to terminate early starting in 2006) at Unit 3, Woodside business Park, Whitley Wood Lane, Reading, Berkshire RG2 8LW, United Kingdom; and office, warehouse, laboratory and manufacturing space through June 2007 at Industrieweg 12, 5627 BS Eindhoven, The Netherlands. The Company considers its facilities adequate; however, additional office, production, and warehouse space will likely be necessary upon FDA approval and subsequent increases in production, marketing, and sales activities in the U.S.

ITEM 3. LEGAL PROCEEDINGS

In July 21, 1998, the Company announced the United States Patent and Trademark Office (USPTO) had informed the Company the USPTO would, as requested by the Company, initiate an interference proceeding (the Interference Proceeding) between the Company and Carbon Medical Technologies, Inc. (CMT), formerly Advanced UroScience, Inc., White Bear Lake, Minnesota, to determine which company was the first to invent pyrolytic carbon-coated micro beads for use in treating urinary incontinence.

Later in 1998, the Company commenced a related lawsuit against CMT for misappropriation of trade secrets (Misappropriation Lawsuit) pertaining to the pyrolytic carbon-coated micro beads, among other things and CMT subsequently brought a counterclaim against the Company with respect to such matter.

Effective October 26, 2001, the Company and CMT entered into a Settlement Agreement terminating the above-referenced legal proceedings; as a part of such Agreement, the Company agreed to dismiss the Misappropriation Lawsuit and to abandon the Interference Proceeding.

Proceeds from the Settlement, totaling $407,000, will be recognized upon the receipt of cash. During the fiscal year ended March 31, 2002, the Company received and recorded a $200,000 gain related to this settlement. In the first quarter of fiscal 2003 the Company received and recorded a $207,000 gain.

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

The Company did not submit any matter to a vote of its security holders during the fourth quarter of its recently completed fiscal year.

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PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

As of the date hereof, there is only a limited public trading market for the Company s Common Stock.

The following table sets forth the high and low bid prices for the Company s Common Stock, as reported in the NASD S Bulletin Board system (market symbol UPST.OB ; formerly UROP.OB) on a quarterly basis, from April 2001 through March 2002. Such quotations represent interdealer prices, without retail markup, mark down or commission, and do not necessarily represent actual transactions. All figures have been adjusted for a one-for-three reverse split effective April 2, 2002.

Fiscal Quarters	Low Bid	High Bid
First Quarter	$4.56	$5.55
Second Quarter	2.55	4.80
Third Quarter	2.40	3.12
Fourth Quarter	2.10	3.15

As of March 31, 2002, approximately 548 holders held the Company s Common Stock of record. Registered ownership includes nominees who may hold securities on behalf of multiple beneficial owners.

ITEM 6. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

THIS DISCUSSION OF THE FINANCIAL CONDITION AND THE RESULTS OF OPERATIONS OF THE COMPANY SHOULD BE READ IN CONJUNCTION WITH, AND IS QUALIFIED IN ITS ENTIRETY BY, THE CONSOLIDATED FINANCIAL STATEMENTS AND NOTES THERETO INCLUDED ELSEWHERE WITHIN THIS ANNUAL REPORT, THE MATERIAL CONTAINED IN THE RISK FACTORS AND BUSINESS SECTIONS OF THIS ANNUAL REPORT, AND THE CAUTIONARY DISCLOSURE ABOUT FORWARD-LOOKING STATEMENTS AT THE FRONT OF PART I OF THIS ANNUAL REPORT.

Overview

Uroplasty, Inc. develops, manufactures, and/or markets medical products in certain segments of the urology, otolaryngology, wound care, 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 primarily 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 (backflow of urine from the bladder to the kidneys). Macroplastique is comprised of soft, irregularly textured, vulcanized, medical grade silicone elastomer implants suspended in a biocompatible carrier solution. When injected via a minimally invasive procedure in the soft tissue of the mid-urethra and bladder neck (in the case of SUI), and at the ureteral orifice (in the case of vesicoureteral reflux), the implants act as a bulking material to restore urinary continence or to eliminate reflux of urine from the bladder to the kidneys.

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

The Company s products are currently sold by direct sales forces in the United Kingdom and The Netherlands, and by a network of distributors in numerous countries outside the U.S., including Western Europe, Australia, and Central and South America. In September 1999, the Company received unconditional approval from the FDA pursuant to a

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previously filed IDE Application to initiate human clinical studies in the U.S. for the Company s primary product Macroplastique in the treatment of female SUI. Through various urological investigators in various clinical sites across the U.S., the Company is currently performing the human procedures specified by the study protocol.

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 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.

In order to reduce costs, an aggregate of 21 positions worldwide were canceled in fiscal 2001 and August 2001, either by terminating employment agreements or through attrition. This reduced salary costs and associated expenses by approximately $75,000 a month. Broken down by department, the reductions are as follows: a $9,000 per month reduction in manufacturing, a $18,000 per month reduction in general and administrative, a $24,000 per month reduction in research and development and a $24,000 per month reduction in selling and marketing. The total severance payments recorded in fiscal 2001 and 2002 were approximately $200,000. There are no restructuring related cash obligations remaining as of March 31, 2002. Company s realized cost reductions were in line with management s expectation. The Company believes increased focus on strategic goals and increased efficiencies will allow the Company to compensate for the eliminated positions.

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 (more fully described in note 1 to the consolidated financial statements), 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. 101, 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 101. 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 policy (see Note 1 to the consolidated financial statements), 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.

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 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.

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Impairment of Long-Lived Assets. Long-lived assets at March 31, 2002 consist of property, plant and equipment and intangible assets. 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 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 year ended March 31, 2002 and 2001. See note 8 to the Consolidated Financial Statements for business segment information.

Results of Operations

Net Sales: The Macroplastique product line accounts for 89% and 92% of total net sales for the years ended March 31, 2002 and 2001, respectively. In fiscal year ended March 31, 2002, net sales of all products were $4,973,976, representing a $694,507 or 12% decrease when compared to net sales of $5,668,483 for fiscal 2001. Management believes the sales decrease was primarily due to aggressive marketing programs targeted toward the urological and gynecological surgeons by large, competitive companies.

Management expects unit sales of Macroplastique will increase in fiscal 2003. This will be a result of a November 2001 product launch with Macroplastique product enhancements and distributor training. The goal is to improve the surgical technique, which will lead to an increased number of doctors performing procedures that will broaden the Macroplastique penetration of the SUI market. There can be no assurance, however, the Company s efforts to increase sales and market penetration will be successful.

Gross Profit: Gross profit was $3,517,167 and $4,355,300 for the years ended March 31, 2002 and 2001, respectively, or 71% and 77% of net sales. Excess capacity, manufacturing inefficiencies due to the manufacturing of the modified products, the additional allowance of approximately $35,000 for inventory obsolescence and the relative higher sales to distributors at lower prices compared to sales to end-users caused the decrease in the gross profit margin. The Company s distributors accounted for approximately 63% and 58% of total net sales in fiscal years 2002 and 2001, respectively.

General and Administrative Expense: General and administrative (G&A) expenses decreased 17% from $1,389,943 during fiscal 2001 to $1,154,419 during fiscal 2002. The decrease in G&A expenses is primarily attributed to the decrease in personnel as a result of the Company s restructuring activities in late fiscal 2001 and in August 2001. Legal expenses were $26,000 higher in fiscal 2002, as a result of the settlement noted below.

Research and Development Expense: Research and development (R&D) expenses decreased $465,177, or 22%, from $2,150,177 during fiscal 2001 to $1,685,000 during fiscal 2002. The decrease in R&D expense resulted principally from a decrease in personnel related to the Company s restructuring activities in fiscal 2001 and fiscal 2002. The human clinical study costs are primarily comprised of physician and medical fees relating to the patient procedures and follow-up examinations, in addition to the costs of monitoring the study, maintaining and evaluating the patient treatment, and follow-up examination data.

Selling and Marketing Expenses: Selling and marketing (S&M) costs decreased $1,079,169, or 49% from $2,185,809 during fiscal 2001 to $1,106,640 during fiscal 2002, as a result of the fiscal 2001 and fiscal 2002 restructuring of the international sales and marketing departments as well as decreased salesperson travel costs and decreased costs relating to trade-shows, conventions and congresses. Furthermore, in the fourth quarter of fiscal 2001, $294,000 was expensed as a termination fee of a distribution agreement.

Other Income (Expense): Other income (expense) includes interest income, interest expense, foreign currency exchange gains and losses, settlement proceeds and other non-operating costs when incurred. Other income (expense) was $178,978 and $(310,270) for the years ended March 31, 2002 and 2001, respectively. Interest income was $19,452 and $54,617 for the years ended March 31, 2002 and 2001, respectively. This decrease is due to the redemption of marketable securities and decreased cash and cash equivalents balances. Interest expense decreased from $27,335 for fiscal 2001 to $25,769 for fiscal 2002 as the result of decreased long-term debt and capital lease balances. 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 s foreign currency exchange loss was $14,373 and $336,958 for the years ended March 31, 2002 and 2001, respectively. At March 31, 2002 and 2001 the Company has $4.0 million and $4.3 million of dollar denominated debt at its Dutch subsidiaries, of which $4.0 million and $3.1 million are short-term dollar denominated obligations that the Company records as currency fluctuations in earnings. The high currency exchange loss in fiscal 2001 was due to a strengthened U.S. Dollar

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compared to the Euro. At March 31, 2002, compared to same date last year, the Euro did not further weaken compared to the dollar. The $200,000 settlement income is the proceeds from the litigation settlement as described in note 5 to the consolidated financial statements. In the first quarter of fiscal 2003 a $207,000 payment was received as final settlement payment, which will be recorded as settlement income in that quarter.

Liquidity and Capital Resources

As of March 31, 2002, the Company s cash and cash equivalent balances totaled $1,046,121. The capital resources existing at March 31, 2002 were derived from operations during the fiscal years ended March 31, 1997 and 1998, plus the net proceeds from the Company s sale of approximately 1.7 million shares of Common Stock in June 1998.

At March 31, 2002, the Company had working capital of approximately $2.1 million. During fiscal year 2002, the Company provided approximately $113,000 of cash by operating activities. This improvement in cash flow was primarily attributable to $200,000 of proceeds from the lawsuit settlement, which reduced the Company s net loss, a $120,334 reduction in inventory balances and a decrease of the accounts receivable by $138,019. An accrued expense totaling $227,000 as per March 31, 2001 for the termination of a French distributor was paid in fiscal 2002. Other current assets, accounts payable, accrued expenses fluctuated due to the timing of payments.

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 March 31, 2002 of $845,431 and $632,102, respectively. As of March 31, 2002, the allowance for inventory obsolescence is $57,000.

The Company has U.S. and international operations. U.S. net operating loss carryforwards cannot be used to offset taxable income in foreign jurisdictions. Furthermore, repatriation of dividends to the U.S. parent may result in additional foreign or U.S. taxes.

The Company s financial condition and results of operations could be significantly 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. 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.

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 PMA submission and review process, and pre-commercialization and market launch costs in the U.S. relating to Macroplastique for the treatment of female SUI.

As a result of the Company s cost reduction activities and the Company s ability to manage the timing of the FDA clinical expenditures, management believes current resources, the funds generated from sale of the Company s products outside the U.S., and the expected proceeds from the rights offering (more fully described in note 1 to the consolidated financial statements), will be adequate to meet the Company s cash flow needs through fiscal 2003 and fiscal 2004, including research and development activities associated with existing products and markets. Without the successful completion of the rights offering, the Company believes the completion of the FDA clinical study could be delayed.

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

	Payments due by period				
	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Notes payable	$ 429,140	29,918	89,754	59,836	249,632
Capital lease obligations	12,393	12,393			
Operating lease commitments	629,539	261,150	315,081	53,308	
Total contractual obligations	$1,071,072	303,461	404,835	113,144	249,632

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

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Company pays royalties, in the aggregate, of three to five percent of net sales of Macroplastique and Bioplastique, 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 licence 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. Royalties are more fully described under Patents, Trademarks, and Licenses.

New Accounting Pronouncements

In August 2001, the Financial Accounting Standards Board issued Statement No. 144, Accounting for the Impairment or disposal of Long-Lived Assets. Statement No. 144 addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes Statement No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of. However, this statement retains the fundamental provisions of Statement No. 121 for (a) recognition and measurement of the impairment of long-lived assets to be held and used and (b) measurement of long-lived assets to be disposed of by sale. Statement No. 144 also supersedes the accounting and reporting provisions of APB Opinion No. 30, Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions, for the disposal of a segment of a business. However, this Statement retains the requirement of APB No. 30 to report discontinued operations separately from continuing operations and extends that reporting to a component of an entity that either has been disposed of or is classified as held for sale. This statement also amends ARB No. 51, Consolidated Financial Statements, to eliminate the exception to consolidation for a temporarily controlled subsidiary. The Company will adopt the provision of Statement No. 144 effective April 1, 2002. The Company has evaluated Statement No. 144 and determined that the pronouncement will have no material impact on the Company s consolidated financial statements.

ITEM 7. FINANCIAL STATEMENTS

The information contained under the headings Consolidated Statements of Operations , Consolidated Balance Sheets , Consolidated Statements of Shareholders Equity and Comprehensive Loss , Consolidated Statements of Cash Flows , Notes to Consolidated Financial Statements and Independent Auditors Report is incorporated herein by reference.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

The Company s Directors and Executive Officers as of March 31, 2002 were as follows:

Name	Age	Position	Director Since	Term expires
Daniel G. Holman	56	Chairman, President, CEO, CFO	1994	2003
Joel R. Pitlor	63	Director	1994	2004
R. Patrick Maxwell	57	Director	1994	2002
Thomas E. Jamison	42	Director	2000	2004
Christopher Harris	43	Vice President International Sales Managing Director UK subsidiary		

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Name	Age	Position	Director Since	Term expires
Larry Heinemann	49	Vice President Marketing & Corporate Development		
Susan Hartjes Holman	48	Vice President Operations & Regulatory Affairs, Secretary		
Arie J. Koole	38	Controller Managing Director Dutch subsidiaries		

All directors are members of the Nominating Committee; all directors except Mr. Holman are members of the Compensation Committee and the Audit Committee.

The Company has entered into Employment Agreements, which are terminable at will by either party upon thirty day written notice, with Mr. Holman, Ms. Holman, Mr. Heinemann, and Mr. Harris, the terms of which, among other things, specify a base salary subject to annual adjustment by mutual agreement of the Company and the Employee, and a severance payment to the employee upon employment termination without cause. The initial salaries, which can be increased annually in the discretion of the Board, were $180,200, $121,000, $78,000 and $74,000, respectively. Any severance amounts payable under the Agreement shall be limited to the Employee s base salary for not less than four months and not longer than twelve months after employment termination, depending on the Employee s years of service. Contemporaneously with the execution of the Employment Agreement, each of the officers executed an Employee Confidentiality, Inventions, Non-Solicitation, and Non-Compete Agreement, certain terms of which specify the Employee shall not disclose confidential information, shall assign to the Company without charge all intellectual property relating to the Company s business which is created or conceived during the term of employment, shall not encourage Employees to leave the employment of the Company for any reason and shall not compete with the Company during the term of employment and for a period of eighteen months thereafter. Also in connection with the execution of these Agreements, the officers were granted varying amounts of stock options to purchase the Company s Common Stock at the fair market value at date of grant of $7.50 per share. In all cases, the options are exercisable for five years or until one year after employment termination (subject to certain termination provisions), whichever date is earlier, and vest in three equal amounts on each one year anniversary date subsequent to the option grant date.

The following paragraphs describe the business experience of each of the Company s directors and officers.

Daniel G. Holman: Mr. Holman has served as Chairman of the Board, President and Chief Executive Officer of Uroplasty, Inc. since February 1994, as Chief Financial Officer from June 1996 to November 1999 and as Chief Financial Officer as of February 2001. He was Executive Vice President of Bioplasty, Inc. from 1973 to 1985, its President from 1985 to 1987, and Secretary from 1986 to March 1992. Mr. Holman has been Chairman of the Board of Bioplasty, Inc. from March 1992, and President and CEO from February 22, 1993 to December 31, 2001. He served as Chairman of the Board and Chief Executive Officer of Bio-Vascular, Inc. from June 1988 to September 1991, served as a director of Genetic Laboratories Wound Care, Inc. from February 1988 until July 1993, and as Vice President from February 1988 through November 1992. Mr. Holman holds a Bachelor of Arts degree in Biology from St. Cloud State University.

Joel R. Pitlor: Mr. Pitlor has been a director since February 1994. He served as a director of Bioplasty from January 1989 until May 1996. For over sixteen years, he has been the owner and manager of a management consulting firm. Mr. Pitlor is presently a Director of Precision Optics Corporation, which is publicly held. Mr. Pitlor holds a Bachelor of Science degree from MIT and serves as Personal Advisor to several CEOs.

R. Patrick Maxwell: Mr. Maxwell was appointed a Director of Uroplasty in April 1994 and elected by the shareholders in August 1997. Mr. Maxwell has over 30 years of experience as a turn around management specialist, an entrepreneur and executive in both the business and non-profit sectors. Mr. Maxwell is Cofounder and a Director of Telnet Services Limited of Auckland, New Zealand since September 1995, Cofounder and Chief Financial Officer of Tele Resources, Inc. since October 1996 and Chief Financial Officer of American Specialty Confections since April 2000. Mr. Maxwell has served on numerous Boards of Directors of both business and charitable organizations. He has a B.A. in philosophy from St. John s University and a Juris Doctor from Northwestern University School of Law.

Thomas E. Jamison: Mr. Jamison was elected a Director of Uroplasty in August 2000. Mr. Jamison is an attorney with the business litigation law firm of Fruth, Jamison & Elsass, P.A. in Minneapolis. From 1996 to 1999, Mr. Jamison served as an investment banker in the Corporate Finance Department of R.J. Steichen & Co. From 1991 to 1996, Mr. Jamison practiced law at Fruth & Anthony, P.A. in Minneapolis. Mr. Jamison graduated magna cum laude from William Mitchell College of Law in 1991.

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Christopher Harris: Mr. Harris joined Bioplasty in October 1989 as Area Sales Manager in the United Kingdom. Since September 1994, he has been the Managing Director of the Company s subsidiary, Uroplasty LTD., in the United Kingdom. In February 1996, Mr. Harris was appointed as Director of Corporate Development and in January 1997 he was appointed Vice President of Corporate Development. In August 2001 he was appointed Vice President International Sales. Mr. Harris, a certified nurse in the United Kingdom, practiced general surgery nursing for two years and operating room nursing for nine years prior to 1989.

Larry Heinemann: Mr. Heinemann joined Uroplasty in September 1998 as Director of Sales for North and South America. In July 1999 he was promoted to Vice President of Sales and Marketing for Uroplasty, Inc. In August 2001 he was appointed as Vice President Marketing & Corporate Development. Prior to joining Uroplasty, Inc., Mr. Heinemann worked for two divisions of C. R. Bard, Inc. From January 1996 to September 1998, he was employed by the Bard Medical Division in the positions of Territory Manager and Sales Training. From May 1987 to January 1996, Mr. Heinemann was employed by the Bard Urological Division in various positions of Sales Consulting and Training Management. Prior to that time, Mr. Heinemann was employed by surgical device divisions of Squibb and Sterling Drug in various sales management positions. Mr. Heinemann holds a Bachelor of Science Degree from the School of Business of Eastern Illinois University and majored in Marketing and Personnel Management. He is a member of SUNA (Society of Urological Nursing Association), and has been serving on the Board as an Industry Liaison for the Upper Midwest Chapter since 1991.

Susan Hartjes Holman: Ms. Holman joined Bioplasty, Inc. in September 1991 as Director of Operations and served as Vice President of Operations and Regulatory Affairs from April 1993 until May 1996. In November 1994, she was appointed Vice-President of Operations and Regulatory Affairs for Uroplasty, Inc. and was elected Secretary in September 1996. Prior to 1991, Ms. Holman was Director of Operations at Bio-Vascular, Inc. in St. Paul, Minnesota from November 1989 to September 1991. Prior to that time, she served at various other pharmaceutical and medical device companies in management-oriented positions in manufacturing, quality assurance, and research. Ms. Holman has Bachelor of Arts degrees in Biology-Microbiology and Biomedical Science from St. Cloud State University, and has done graduate work in the biological sciences. Ms. Holman is a senior member and a Certified Quality Auditor of the American Society for Quality, served several years on its Executive Committee and subcommittees, and is a member of the American Society of Microbiology, and the Henrici Society for Microbiologists. She has served on several national and international standards committees.

Arie J. Koole: Mr. Koole joined Bioplasty in May 1993 as Financial Manager in The Netherlands. Since January 2000 he has been the Managing Director of the Company s subsidiaries in The Netherlands. In June 1996, Mr. Koole was appointed as Director of Finance and in January 2000, Mr. Koole was appointed as Controller. From 1987 to 1993, Mr. Koole was a financial auditor with the international accounting firm Deloitte & Touche in The Netherlands. Mr. Koole has a bachelor degree in Business Economics.

Mr. Holman and Ms. Holman became husband and wife in June 1999.

ITEM 10. EXECUTIVE COMPENSATION

The information contained under the heading Executive Compensation in the Proxy Statement is incorporated herein by reference.

ITEM 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information contained under the heading Principal Shareholders in the Proxy Statement is incorporated herein by reference.

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information contained under the heading Certain Transactions in the Proxy Statement is incorporated herein by reference.

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ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits incorporated by reference (Rule 12b-23). The following Exhibits are incorporated by reference to the Company s Registration Statement on Form 10SB filed July 10, 1996 or the Company s Annual Report on Form 10-KSB for the fiscal year ended March 31, 2000.

Number	Description
2.1	First Amended Joint Plan of Reorganization (Modified) of the Company dated January 31, 1994 (Filed as Exhibit 8.1 to Form 10SB)
3.1	Articles of Incorporation of Uroplasty, Inc. (Filed as Exhibit 2.1 to Form 10SB)
3.2	Bylaws of Uroplasty, Inc. (Filed as Exhibit 2.2 to Form 10SB)
4.1	Form of Stock Certificate of the Company representing shares of the Company s Common Stock (Filed as Exhibit 3.1 to Form 10SB)
10.1	Settlement Agreement and Release dated November 30, 1993 by and between Bioplasty, Inc., Bio-Manufacturing, Inc., Uroplasty, Inc., Arthur A. Beisang, Arthur A. Beisang III, MD and Robert A. Ersek, MD (Filed as Exhibit 6.1 to Form 10SB)
10.2	Purchase and Sale Agreement dated December 1, 1995 by and among Bio-Vascular, Inc., Bioplasty, Inc., and Uroplasty, Inc. (Filed as Exhibit 6.2 to Form 10SB)
10.3	License Agreement dated December 1, 1995 by and between Bio-Vascular, Inc. and Uroplasty, Inc. (Filed as Exhibit 6.3 to Form 10SB)
10.4	Lease Agreement dated January 10, 1995 between Summer Business Center Partnership and Uroplasty, Inc. (Filed as Exhibit 6.4 to Form 10SB)
10.5	Unsecured $640,000 Promissory Note dated March 30, 1994 by and between Bioplasty, Inc., Uroplasty, Inc. and Bioplasty Product Claimants Trust (Filed as Exhibit 6.5 to Form 10SB)
10.6	Agreement and Satisfaction dated January 30, 1995 by and between Bioplasty Product Claimants Trust and Bioplasty, Inc. (Filed as Exhibit 6.6 to Form 10SB)
10.7	Asset Sale and Satisfaction of Debt Agreement dated June 23, 1995 by and between Bioplasty, Inc. and Uroplasty, Inc. (Filed as Exhibit 6.7 to Form 10SB)
10.8	Executory Contract Assumption Stipulation dated December 28, 1993 by and between Bioplasty, Inc., Uroplasty, Inc., and Collagen Corporation (Filed as Exhibit 6.8 to Form 10SB)
10.9	Settlement and License Agreement dated July 23, 1992 by and between Collagen Corporation, Bioplasty, Inc., and Uroplasty, Inc. (Filed as Exhibit 6.9 to Form 10SB)
10.10	Employment Agreement between Uroplasty, Inc. and Daniel G. Holman dated December 7, 1999. (Filed as Exhibit 10.10 to Form 10-KSB/03-31-2000.)
10.11	Employment Agreement between Uroplasty, Inc. and Christopher Harris dated December 7, 1999. (Filed as Exhibit 10.11 to Form 10-KSB/03-31-2000.)
10.12	Employment Agreement between Uroplasty, Inc. and Susan Holman dated December 7, 1999. (Filed as Exhibit 10.13 to Form 10-KSB/03-31-2000.)
10.13	Employment Agreement between Uroplasty, Inc. and Larry Heinemann dated December 7, 1999. (Filed as Exhibit 10.14 to Form 10-KSB/03-31-2000.)
10.14	Agreement, dated October 14, 1998, by and between Uroplasty, Inc. and Samir M. Henalla (pertaining to Macroplastique Implantation System). (Filed as Exhibit 10.15 to Form 10-KSB/A /03-31-2001)

(b) The following exhibits are filed as part of this report:

Number	Description
13.0	Financial Statements
21.0	Subsidiaries of the Company
23	Independent Auditors Consent

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SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: June 11, 2002

UROPLASTY, INC.
By: /s/ DANIEL G. HOLMAN
Daniel G. Holman
President, Chief Executive Officer,
Chief Financial Officer (Principal Financial Officer),
Director (Principal Executive Officer)

In accordance with the Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

Name	Title / Capacity	Date
/s/ DANIEL G. HOLMAN Daniel G. Holman	President, Chief Executive Officer Chief Financial Officer, Director (Principal Executive and Financial Officer)	June 11, 2002
/s/ ARIE J. KOOLE Arie J. Koole	Controller (Principal Accounting Officer)	June 11, 2002
/s/ JOEL R. PITLOR Joel R. Pitlor	Director	June 11, 2002
/s/ R. PATRICK MAXWELL R. Patrick Maxwell	Director	June 11, 2002
/s/ THOMAS E. JAMISON Thomas E. Jamison	Director	June 11, 2002