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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health



National Institutes of Health Commercialization Assistance Program
(NIH-CAP)

Company Profile

Industry Sector: Medical Devices

Company Overview: Urovalve is a development stage company that seeks to commercialize superior medical devices that address problems with urinary flow and control. The Company has developed a novel bladder management system intended for men who suffer urinary retention (inability to empty the bladder).

Target Market(s): Urinary retention affects up to 6 million men as a result of many causes, including acute obstruction of the urethra, hypertrophy of the prostate gland (BPH), detrusor muscle atrophy due to aging and diabetes, and neuromuscular dysfunction due to spinal cord injury, muscular sclerosis and other causes. The global market for devices to manage urinary retention has been estimated at up to \$3.2 Billion in 2006, with a projected CAGR of 6–12% through 2012. The need for improved devices has been frequently stated by patients, urologists and caregivers. The primary target markets will be urologists and urology outpatient centers.

Management

Leadership:

Harvey D. Homan, President and CEO
Thomas W. Winegar, VP Engineering and Development

Scientific Advisory Board:

Subbarao Yalla, MD, Professor of Surgery (Urology), Harvard Medical School;
Michael Siroky, MD, Professor of Surgery (Urology), Boston Medical Center;
Joseph V. DiTrollo, MD, Clinical Professor of Surgery, UMDNJ - New Jersey Medical School;
Bill Van Buskirk PhD, Distinguished Professor Mechanical Engineering, NJIT
Vince DeCaprio, PhD, formerly CEO, President and Vice Chairman, Vyteris, Inc.
Carl Jacobs, PhD, formerly VP Operations and Engineering, Datascope, Inc.

Key Value Drivers

Technology: Urovalve owns patents for remote operated miniature magnetically-controlled valves (US 5,366,506; US 6,066,088) that control fluid flow through small tubes. The Surinate® bladder management system incorporates the valve into a unique (patent applied for) silicone catheter that is designed to be easily and completely inserted into the urethra, remain in place for up to 30 days and be removed without surgery. The patient controls bladder emptying using an external magnetic wand.

Competitive Advantage: The Surinate® bladder management system is designed to return control of bladder emptying to the patient, free the patient from external tubes and collection bags and prevent bacterial migration into the urinary tract that causes a high incidence of urinary tract infections with current devices (850,000 per year in US acute care facilities).

Plan & Strategy: Urovalve plans to complete clinical testing, obtain regulatory approval and launch the Surinate® system in 2009. Initial focus will be on select VA Centers while reimbursement and pricing is secured. The Company will explore strategic partnerships for commercial expansion.

*Technology funded by the NICHD and being commercialized under the NIH-CAP.

Product Pipeline

Surinate® Bladder Management System

Urinary retention (males)

- Successfully completed clinical feasibility study on alpha version
- completed development and manufacture of improved beta version
- Ph 2/3 to be completed early 2009

Incontinence (males)

- concept stage

Urinary retention (females)

- concept stage

Incontinence (females)

- concept stage

