



Pluromed, Inc. Announces FDA Approval for BackStop™

Pluromed, Inc. announced approval by the U.S. Food and Drug Administration (FDA) for [BackStop™](#), a device used in ureteroscopic kidney stone management procedures. BackStop was approved as a Class II device under the pre-market notification 510(k) process.

Woburn, Massachusetts ([PRWEB](#)) September 23, 2009 -- [Pluromed, Inc.](#) announced approval by the U.S. Food and Drug Administration (FDA) for BackStop™, a device used in ureteroscopic kidney stone management procedures. [BackStop](#) was approved as a Class II device under the pre-market notification 510(k) process.

Backstop™ is based on Pluromed's proprietary [Rapid Transition Polymers](#) (RTP™) that are liquid at low temperature and transition to gel at body temperature; the transition is reversible via cooling and the gel is completely dissolvable. BackStop is used in the treatment of kidney stones, a disease estimated to affect 5 million people worldwide annually. A common method of treating stones is intracorporeal lithotripsy where the stones are fragmented using laser energy or another energy modality in a minimally invasive procedure. The BackStop gel forms a plug above the stones in the ureter and prevents stone migration during fragmentation. After the stones are fragmented, the gel is dissolved with saline and exits the body. BackStop offers the potential to reduce operating time and complexity, and significantly improve "stone free" rates for patients.

"Gaining our first FDA approval is a special milestone for Pluromed," said Jean-Marie Vogel, Pluromed's CEO. "We are pleased to be executing the plan we presented to the Massachusetts Life Sciences Center that resulted in the Accelerator Loan, funding that has contributed to our substantial progress in a very short period of time."

In April of 2009, Pluromed received a \$500,000 Accelerator Loan from the Massachusetts Life Sciences Center, a quasi-public agency tasked with implementing Massachusetts' ten-year, \$1 billion Life Sciences Initiative. The Accelerator Loan Program provided \$3.4 million in working capital to seven early-stage life sciences companies, including Pluromed. The program seeks to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences by providing working capital to promising early-stage companies.

"Adding United States FDA approval is an exciting step as we move towards making BackStop broadly available to urologists around the world," said James Wilkie, Pluromed's Vice President of Operations. BackStop is also approved in Europe and Canada. "It's a product that can benefit both the surgeon and the patient."

In addition to BackStop, Pluromed has developed a family of Rapid Transition Polymer products for cardiac and vascular surgery. [LeGoo™](#), Pluromed's flagship product which is commercially available in Europe, is a gel used to temporarily stop blood flow through a blood vessel, providing surgeons with a bloodless field in which they can perform a bypass procedure. When cooled, the gel plug liquefies and dissolves into the bloodstream, and is then excreted in urine. [Pluromed's LeGoo](#) is the only completely atraumatic method of temporarily occluding a blood vessel.

"Pluromed is the second of our portfolio companies to announce FDA approval this week for an innovative medical product that will improve human health." Said Dr. Susan Windham-Bannister, President & CEO of the



Massachusetts Life Sciences Center. "These approvals are coming just five months after we announced the Accelerator loans. The approval of BackStop is another example of the Center's commitment to promoting good science that will bring commercialization and job growth to Massachusetts. We are very proud to have Pluomed as part of our investment portfolio."

About Pluomed, Inc.

Pluomed, Inc., Woburn, Massachusetts, founded in 2003, is pioneering the use of atraumatic gel plugs to improve the safety, efficacy and economics of medical interventions. These products address a broad surgery market that includes cardiac and vascular surgery, prostate, kidney and liver surgery, plastic/reconstructive surgery, trauma/battlefield applications and the treatment of kidney stones. They are based on the Company's patented rapid phase transition polymer technology; Pluomed Rapid Transition Polymers™ (RTP™) are liquid at low temperature and quickly transition to a high viscosity gel at body temperature. For more information, please visit www.pluomed.com

About the Massachusetts Life Sciences Center

The Massachusetts Life Sciences Center is a quasi-public agency of the Commonwealth of Massachusetts tasked with implementing the Massachusetts Life Sciences Act, a ten-year, \$1 billion initiative that was signed into law in June of 2008. The Center's mission is to create jobs in the life sciences and support vital scientific research that will improve the human condition. This work includes making financial investments in public and private institutions that are advancing life sciences research, development and commercialization as well as building ties between sectors of the Massachusetts life sciences community. For more information, visit www.masslifesciences.com.

About the Life Sciences Accelerator

In order to expand life sciences-related employment opportunities, promote health-related innovations and stimulate research and development, manufacturing and commercialization in the life sciences, the Life Sciences Accelerator Program provides loans to companies engaged in life sciences research and development, commercialization and manufacturing in Massachusetts. Target entities are generally early-stage life sciences companies with a high-potential for technology commercialization, rapid growth, and downstream private equity financing. The program is designed to help sustain these companies through a critical stage of development and to leverage additional sources of capital to bring cutting edge innovation to the marketplace. Accordingly, the Program places special priority on providing matching funds for grants or awards from a variety of sources.

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