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Urotronic's Optilume BPH Drug Coated Balloon offers Urologists an In-Office Procedure that Opens the Flow of the Prostate without the Damage

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CEOCFO: ***Mr. Perry, what is the concept behind Urotronic and Optilume?***
Mr. Perry: Urotronic is a start-up medical device company based in Minneapolis, MN. Our focus is on the treatment of urinary tract disorders that are common in the field of urology. We have raised over $40 million to support two products; Optilume to treat urinary tract strictures, and the second, Optilume BPH for enlarged prostate or Benign Prostate Hyperplasia. With both products, the Optilume drug coated balloon is used to exert gentle radial force to dilate the urethra to overcome the narrowed obstruction present before treatment providing greater flow of urine exiting the body. The distal end of the catheter has a semi-compliant inflatable balloon that is coated with a proprietary drug coating containing the active pharmaceutical paclitaxel which prevents the newly dilated area from scarring down or re-narrowing causing obstruction to flow.

OPTILUME
DRUG-COATED
UROLOGY BALLOON

CEOCFO: ***Would you tell us what the technology is, what the concept is, why it works and why we need it?***
Mr. Perry: The technology was created by our founder, Dr. Lixiao Wang, who created the first drug coated balloon for peripheral vascular applications with a company called Lutonix, that was sold to C. R. Bard, Inc. (NYSE: BCR) https://evtoday.com/news/bard-acquires-lutonix, which was then acquired by Becton Dickinson and Co (NYSE: BDX). The product is now the standard of care for peripheral vascular interventions world-wide due to the outstanding clinical results. Dr. Wang maintained the non-vascular applications to the technology which focus on the urology and gastroenterology field.

The Optilume BPH procedure is a minimally invasive treatment that gives urologists the opportunity to offer an office-based or outpatient treatment option that may provide relief to men who are looking for an alternative to currently available BPH treatment offerings. A First-in-Man safety trial was performed in Latin America on 80 patients demonstrating excellent results. We are currently enrolling 160 patients in a US based clinical study called "PINNACLE" at 20 sites across the country.

More than 12 million American men are reported to suffer from enlarged prostates or Benign Prostatic Hyperplasia (BPH) and over 750,000 new cases are diagnosed each year. Millions of men struggle to deal with the symptoms of BPH, including frequency, nocturia, intermittency, urgency, weak stream and straining to urinate as a result of being refractory or non-responsive, or are unwilling to deal with the side effects of medical therapy, or reluctant to undergo an invasive surgical procedure requiring general anesthesia.

"The Optilume BPH balloon pairs innovative design with powerful drug therapy to provide a simple, anatomy sparing in-office procedure that doesn't surgically cut, burn, lase, steam or leave anything behind in the prostate like the other BPH technologies," said Dr. Steven Kaplan, Professor, Icahn School of Medicine at Mount Sinai and Director of the Men's Wellness Program, Mount Sinai Health System in New York and the Principal Investigator of PINNACLE clinical study. "This technology holds tremendous promise."

The promise of our technology is to gently dilate and expand the lumen creating micro tears or fissures in the tissue, which then allows the drug to come off and take residence in the tissue preventing the cascade of scar tissue or re-narrowing from developing. We have now completed three clinical studies on our two products with encouraging results that could be very disruptive to current technologies.

CEOCFO: ***Have similar approaches been tried?***
Mr. Perry: Yes, dilation in various forms with balloons, rigid rods and even various cutting procedures have been done for many years back to the days of the Egyptians, but they are not curative – these procedures all lead to high rates of recurrence. It is the combination of dilation with circumferential drug delivery that is the key to our success.

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CEOCFO: ***What are the properties of the balloon that make it unique to the application? Where does that come into play in either allowing the drug to coat it or on the whole process?***
Mr. Perry: The balloon is a proprietary design to match the elastic properties of the urinary tract tissues. Dynamic compliance is needed to provide the dilation force necessary to expand the tissue overcoming the obstruction, and then adequately releasing the novel drug coating to provide the durable results. The balloon catheter is very robust and can withstand high pressures in the range of 10-15 atmospheres.

CEOCFO: ***What has been the response from the medical community that is aware of what you are doing?***
Mr. Perry: They have been very supportive of our efforts to introduce disruptive technology that will ultimately benefit the patients that they treat. We have had several worldwide presentations reporting the outcomes of our clinical studies. We even received an award for 'Best New Innovation in Urology' at the World Congress of Endourology this past year in Paris, France. Overall, there is a universal excitement about having a drug and device combination product that is differentiated from the products that are currently available on the market.

CEOCFO: ***How does this compare cost wise with what is available now?***
Mr. Perry: We have two economic studies that are being done; one at the Mayo clinic involving all three campuses, Florida, Rochester and Arizona and also one being done in the United Kingdom with NHS (National Health Service) hospital system. The data is still being collected, but it appears that we will provide an economic advantage and reduce costs overall due to the retreatment rates that are common for the diseases that we treat.

CEOCFO: ***I see on your website that Optilume is available in Canada and New Zealand today?***
Mr. Perry: Yes. That is the Optilume stricture product. We are also approved in Israel and are less than a month away from CE (European) approval and we expect US approval late next year. We recently submitted the Optilume BPH product

for CE and Canadian approval and plan to submit for US approval next year after completing enrollment in our US clinical study.

CEOCFO: ***You mentioned raising over $40 million. How far will that take you?***
Mr. Perry: We have raised $41 million through our Series B financing. We are currently raising our Series C financing of $20 million. The Series C will take us all the way through our regulatory approvals and start our commercialization efforts in a limited number of geographies, including the US.

CEOCFO: ***Do you find that as the concept is relatively easy to understand, investors show more interest?***
Mr. Perry: Absolutely. The sheer concept of a combination product (drug + device) seems better so long as it is safe and easy to use. Also, note that there are several companies in the urology community that do not have a stricture or BPH presence. If you were to look at a standard urology practice, the number two diagnosis, on a month over month basis is BPH or enlarged prostate. Therefore, if you have a product that is disruptive in a very large market, people take notice quickly.

CEOCFO: ***What surprised you since you started on this venture in terms of the medical or business side?***
Mr. Perry: I think the biggest surprise is just the amount of time that everything takes. We have a small but very capable team and have been hit with our share of unexpected challenges that have unfortunately added time and expense to our program. These challenges come mostly from the regulatory agencies that ask you to do additional tasks that you have not forecasted for both time and expense. It is also hard to enroll patients in a clinical study for an elective procedure when COVID hits and shuts down everything. We lost 3 months of time and are just now starting to enroll patients again.

CEOCFO: ***There are so many companies to look at in health. Why does Urotronic standout?***
Mr. Perry: We have a highly disruptive technology. I have often said that our Optilume stricture product will be a paradigm change. Once physicians see our clinical data and have an opportunity to use our product, they will not go back to what they have been doing before. There is no competition in this space, so we fully expect that paradigm change to happen, which will significantly benefit patients worldwide. For BPH, it is a crowded market with lots of technology and innovation, but the current technologies are all an iteration on a similar approach – Attack the prostate! Whether burning, vaporizing, steaming, or leaving a permanent implant behind, current solutions are damaging to the anatomy and come with unacceptable drawbacks to patients. We believe it is time to explore a completely different approach—one that opens the flow without the damage. And that's Optilume BPH – a highly disruptive technology that we believe men will seek out for treatment.

Lastly, and this is really a big thing - physician training and adoption. In the previous companies that I have worked, a lot of time and money is spent on physician training to ensure they provide best in class outcomes for their patients and feel comfortable using your product. There is a lot of hand holding that goes on within the medical device industry to ensure a product is successful. With Optilume stricture and BPH, we are asking physicians to do what they are already comfortable doing – balloon dilation, which they learned in residency. After 2-3 procedures with our product they get it. It is fun to watch physicians in our clinical studies adopt it so quickly. That alone, when combined with the other things I have mentioned, is the reason why we standout and are so exciting.