

Bluewind Medical

- **Investment Rational**

BlueWind Medical develops innovative neuromodulation technology with the potential to treat multiple medical conditions and is focused on the treatment of Overactive Bladder (OAB) with the RENOVA iStim™ implantable device. An estimated 546 million people are affected worldwide by OAB, of which 423 million will have urge incontinence (UI).¹ BlueWind completed enrollment of its pivotal OASIS study in November 2021.

- **Business Strategy**

BlueWind will launch its RENOVA device in the U.S. after completing its OASIS pivotal study and filing for FDA clearance. Reimbursement must be established for payment funded by the U.S. Centers for Medicare & Medicaid services and commercial insurance payers. Targeted physician marketing and a direct-to-patient strategy will be employed to foster adoption and bring patients into the care continuum.

- **Core Technology**

BlueWind Medical's core technology, the RENOVA iStim™ device, is implanted in a single short outpatient procedure in less than 30 minutes utilizing local anesthesia without the side effects of pharmacotherapy and providing a less invasive solution compared to other surgical therapies. BlueWind Medical addresses the concerns of patients waiting on the sidelines for a more effective and safer therapy.

- **Product Profile/Pipeline**

RENOVA development has been completed with continued efforts focused on production scale up. In parallel to the preparations for market launch the team is working on multiple development initiatives such as re-design of the wearable to support longer lifetime, development of supporting software to provide a holistic envelop for the physician and patients and even an ASIC based implant. Mid-term development initiatives include injectable implantation procedure development. Longer term R&D efforts will potentially also focus on application of the platform technology to other disease states.

- **What's Next?**

BlueWind Medical will continue to build out its U.S. and European commercial team, fund additional clinical studies to support reimbursement efforts and expand indications while continuously working on new research and product development initiatives.
