

Innovalve TWIST Technology: A Novel Approach to Transcatheter Mitral Valve Replacement Challenges Eyal Baror

Company name INNOVALVE BIOMEDICAL * Website WWW.INNOVALVEMED.COM * CEO name EYAL BAROR *

Medical Device* • Why does cardiovascular disease remain the number ONE target for MedTech innovation?

o Executive Summary / Investment Rational The development of a transeptally delivered mitral valve replacement system is central to broadening options for patients with MR. Challenges include delivery, anchoring at the mitral annulus, regurgitant sealing, and avoidance of LVOT obstruction. There is currently no TMVR system which is FDA approved, nor a system in a pivotal trial targeting a large MR population. Innovalve completed the development of its TMVR system. Innovalve started its clinical trials by the end of 2021, in both US (as part of US-EFS trial) and EU. To-date, Innovalve implanted 38 cases (24 of which in the US-EFS trial), with excellent clinical results which will be presented.

o Core Technology The Innovalve TMVR is a one-piece device comprised of an atrial skirt, a ventricular cylindrical stent housing the valve prosthesis, and 6 circumferential arms. Following positioning of the delivery across the mitral valve, the arms are extended beneath the native leaflets and rotated. This maneuver engages the subvalvular apparatus wrapping the native mitral tissue around the device, which becomes secured between the arms and the cylinder upon deployment, providing for robust anchoring and sealing. The chance of LVOT obstruction is minimized by grasping and shifting the native anterior leaflet away from the outflow tract. In addition, the prosthesis is usually canted towards the inferior wall, away from the LVOT, due to the mechanism of chordal anchoring. Innovalve TWIST is the only TMVR device with robust anchoring and sealing of the native mitral valve annulus, with a simple and quick 1-stage approach, low risk of LVOT obstruction, and with positive LV re-modeling.

o Product Profile/Pipeline Innovalve plans completing its EFS / FIH trials by mid-2024, and submitting its Pivotal-IDE request to FDA.

o Business Strategy Confidential

o What's Next? Confidential