TendoMend

A new horizon in tendon repair

Innovative Surgical Device for Tendon Rupture Repair and Additional Indications

COMPANY OVERVIEW

TendoMend Ltd, is a private Israeli medical device start-up company established on beginning of 2019 and is based in Nazareth, Israel. The company has developed an innovative Dynamic Tendon Grip (DTG™) surgical device to replace the traditional highly time-consuming and nonunified suturing techniques of tendon rupture repairs, which are associated with a high prevalence of complications and revision surgery. The device was conceptualized, designed and built by an experienced team of medical device entrepreneurs and senior engineers in close collaboration with Israel's leading orthopedic surgeons.

Our vision at Tendomend is to become a leading manufacturer and supplier of next generation innovative surgery devices for tendon laceration and rupture surgery and other end-to-end anastomoses of orthopedic soft tissues such as ligaments.

The company has established a core proprietary technology that fulfills a key unmet need and challenge within the orthopedic space, by providing a solution for replacing existing tendon and soft tissue suturing. The currently available suturing techniques fail to provide satisfactory post-operative outcomes. Surgery for repair of hands tendon ruptures is associated with a greater than 25% complication rate with over 7% requiring revision surgery and has been selected as the first indication for the use of the Company's innovative device.

TendoMend is a portfolio company of NGT3VC (http://www.ngt3vc.com/). The Company has raised $900K from the Israel Innovation Authority and NGT3 VC at its establishment. An additional $1.0M has raised as SAFE investment from Arbelon Holdings (https://www.arbelon.com/), Lev Dies (http://www.lev-dies.com/), and private investors, includes leading Israeli and U.S. surgeons from The Advanced Centers of Orthopedic (CAO - https://www.cfaortho.com/), the largest ambulatory orthopedic body in the US.

OUR VISION

TendoMend's vision is to become a leading manufacturer and supplier of next generation innovative surgery devices for tendon rupture surgery and other end-to-end anastomoses of orthopedic soft tissues including ligaments.

KEY ADVANTAGES

- Proprietary, Innovative & Affordable Solutions for today's unmet need in tendon rupture repair surgery as well as for other orthopedic soft tissue anastomoses.
- Ergonomically Designed, Simple, User-friendly, Safe and Effective, Reduces Risks and Complications, Significantly Improves post-operative outcomes.

MANAGEMENT TEAM

Ehud Almon, Co-founder & CEO, a successful serial entrepreneur and with over two decades of experience in leading public and private medical device start-ups

Dr. Ioannis Valavanis, Co-founder & Co-Inventor, a leading Greek Orthopedic surgeon and ex-director of the orthopedic department at CAT hospital in Athens, Greece

Dr. Yuval Shezifi, Inventor & CTO, a highly experienced bio-medical engineer who has been instrumental in developing many innovative medical devices

NGT3 VC an Israeli Medical device VC and incubator

ADVISORY BOARD

Prof. Martin Boyer, Co-Chief, Hand & Microsurgery Service, Washington University Immediate previous President of the American Society for Surgery of the Hand (ASSH)

Prof. James Chang, Chief, Division of Plastic & Reconstructive Surgery, Stanford University Medical Center, J&J Distinguished Professor of Surgery (Plastic Surgery) & Orthopedic Surgery Hand & Microsurgery, former president of ASSH

Dr. Morris Brian Polsky, Co-founder of The Centers for Advanced Orthopedics (https://www.cfaortho.com/); a board-certified, fellowship-trained orthopedic surgeon specializes in minimally invasive arthroscopic surgery; Sports medicine and sports injuries; Joint replacement and Hand and upper extremity injuries. Dr. Polsky and two of his hand surgeon partners are among the investors in TendoMend

Dr. Yona Yaniv, Director Hand Surgery Department, Sheba Medical Center, Israel

Dr. Mordechai Vigler, Head of the Hand Surgery unit at Hasharon Medical Center, Israel

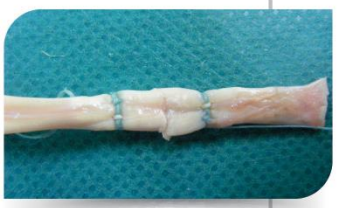
Dr. Assaf Kadar, Senior Hand Surgeon at Rabin Medical Center, Israel and co-inventor of the Turkey animal model for tendon repair surgery

Dr. Yafi Levanon, Deputy of Occupational Therapy, Hand Rehabilitation Department, Sheba Medical Center, Israel

THE DTG™ DEVICE

The Company's Dynamic Tendon Grip (DTG™) device, is comprised of an implant and a dedicated applicator; both of which are single-use. The unique UHMEPR suture knots array configured implant is based on several knots, known as the Whoopie Sling. The Whoopie Sling is an adjustable loop that locks under stress and functions as a ratchet, establishing a grip that externally embraces the entire tendon. The mechanism of the DTG™ implant enables an applied controlled preloaded force, as well as stable and accurate alignment between the two torn tendon stumps. It prevents damage to the tendon tissue integrity, allowing for a stronger, less traumatic repair, while maintaining a low profile, to permit smooth gliding through the pulleys.

MARKET POTENTIAL



The global market potential for the Company's DTG™ device for hand tendons is estimated to be $640M, based on a conservative pricing of $700 per DTG™ device kit. The market potential for other upper and lower extremity tendon rupture repairs (Achilles, Quadriceps and Bicep) increases the market potential by a further $270M.

The company plans to expand its DTG™ technology by continually investing in the R&D and engineering required to deploy the necessary design modifications needed for end-to-end anastomosis of orthopedic soft tissues in Arthroscopic surgery. These include indications such as Anterior Cruciate Ligament (ACL) ruptures and Rotator Cuff Repair.

BUSINESS STRATEGY

A single DTG™ device kit will be sold for a single tendon repair. For each tendon the surgeon will utilize a kit comprising of two tendon holders and a disposable applicator contains a preloaded implant. The primary initial indication focuses for the DTG™ device will be hand tendon laceration repairs. Secondary indications include larger extremity tendon rupture repairs (Achilles, Biceps, Quadriceps, Patella). These well-established markets represent the key areas of greatest unmet need and therefore offer the greatest opportunity for Tendomend and the shortest path to market and revenue generation. TendoMend will first enter the US. market following the receipt of FDA clearance expected during Q2 2023. The initial market release will be a soft launch in which the device will be sold to a limited number of US hospitals that will serve as Centers of Excellence. The initial market launch will be driven through leading orthopedic hand surgeons at key US hospitals, who will serve to extensively promote and endorse the DTG™ device within the surgical community. Entry into the European market is expected following CE-Mark clearance by end of 2023. The Marketing and Sales of the DTG™ device will be driven through selective distributors and strategic partners that operate within the orthopedic space.

INTELLECTUAL PROPERTY (IP) STRATEGY

Tendomend maintains a robust and growing IP portfolio. National applications on the initial technology titled, "Advanced Tendon Grasping Devices and Devices for Their Application" was allowed in the US (June 2021); and in Europe (EPO, April 2021). In addition, a PCT patent application titled "Tissue Repair System" and a provisional patent application titled "Systems Methods for a Set of Proximity Markers Disposed on Opposite ends of Connective Tissue" were submitted in Sep 2021 and March 2021 accordingly. The company sees strategic value in protecting its IP assets and has assigned Dr. Guy Kotlizky, a senior patent attorney to manage its IP portfolio and strategy.

REGULATORY STRATEGY

TendoMend expects FDA 510(K) clearance by end of Q1 2023 and anticipates CE-Mark Approval in the EU by end of 2023.

VALUE PROPOSITION FOR INVESTORS

TendoMend offers high potential growth in large global orthopedic markets facing critical unmet needs.

The Company is seeking to raise US $3.0M

Proceeds will be used to meet key milestones over the next 24 months

- Semi-commercial manufacturing of the DTG™ device for hand tendon surgery
- Helsinki Approval and FIH Trial with the DTG™ device (10 subjects)
- FDA and CE-Mark Clearances
- Soft launch, post marketing study and Initial brand awareness and sales
- Modified the DTG™ device and expand its use for other tendons surgery
- Establishing formal collaboration with strategic partners

A detailed roadmap with clear milestones is available upon request.

CURRENT STATUS & MILESTONE ACHIEVEMENTS

- DTG™ technology development and completion of advanced DTG™ prototype for hand tendon repair.
- Manufactured product for pre-clinical and cadaver trials and for demonstration purposes with leading surgeons in Israel and the US.
- Successful completion of efficacy hand cadaver biomechanical trials.
- Successful completion of pre-clinical safety and efficacy trials with follow-up and histological evaluation in animal tendon (turkey) model.
- Three separated patent applications together with an Expert search, confirming strength of broadened IP.
- Helsinki approval for FIH clinical trial (in process).
- Scientific Advisory Board and Key Opinion Leaders and Surgeons recruited.

FOR MORE INFORMATION

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