ReWalk Announces 510k FDA Submission for ReStore™ Exo-Suit for Stroke Rehabilitation

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Innovation in robotic rehabilitation technology will provide the first-of-its-kind medical device to rehab clinics nationwide, to treat the millions of patients with lower limb disability due to stroke

MARLBOROUGH, Mass. and YOKNEAM ILIT, Israel, Feb. 19, 2019 /PRNewswire/ -- ReWalk Robotics, Ltd. (Nasdaq: RWLK) ("ReWalk" or the "Company"), a leading manufacturer of robotic medical devices for individuals with lower limb disabilities, today announced the submission of its 510k application to the U.S. Food and Drug Administration (FDA) for the ReStore™ exo-suit for gait training during stroke rehabilitation. The 510k application submission marks the next step, and a significant milestone in the process of commercialization.

Strokes are a major cause of serious long-term disability, with over 795,000 people suffering a stroke each year in the U.S. alone. Five million people are permanently disabled each year by strokes globally, according to the World Health Organization (WHO) figures.*

Unveiled in 2017, the novel ReStore soft exo-suit is designed to be a versatile, cost-effective gait therapy solution. The soft, garment-like design allows variability of movement in combination with first-of-its-kind active ankle assistance that adaptively synchronizes with the patient's natural gait, to facilitate functional gait training activities. The device also provides therapists the ability to adjust and optimize a patient's treatment using real-time analytics.

"This submission marks a significant milestone for robotic rehabilitation technologies and represents a clear, distinct evolution in powered rehabilitation solutions," said Larry Jasinski, ReWalk CEO. "The ReStore is a versatile device which will provide high-level, reproducible care for a broad range of a clinic's gait training clients, at a price point accessible to many more clinics than current technologies. The company is proud to continue its work in revolutionizing devices for mobility challenged individuals, and to be at the forefront of next-gen development in medical exoskeletons."

The 510k submission follows the completion of a nationwide clinical study, with 44 patients enrolled across five leading rehabilitation centers in the United States:

- The Shirley Ryan AbilityLab in Chicago, IL
- Spaulding Rehabilitation Hospital in Boston, MA, in partnership with Boston University College of Health and Rehabilitation Sciences: Sargent College
- MossRehab Stroke and Neurological Disease Center in Elkins Park, PA
- TIRR Memorial Hermann in Houston, TX
- Kessler Foundation in West Orange, NJ

"As part of the multi-site study of the ReStore exo-suit, we applied the device to a broad range of individuals with post-stroke gait dysfunctions. The device allowed the study participants to walk effectively and efficiently, and we are encouraged with the potential of this technology to interact with and enhance everyday clinical care" explained Arun Jayaraman, PT, PhD who is Director of the Max Nader Lab for Rehabilitation Technologies & Outcomes Research at Shirley Ryan AbilityLab and lead investigator for the ReStore clinical study.

Following CE submission in Q4 of 2018, ReWalk anticipates commercializing the ReStore device for use by stroke patients and rehab clinics in Europe

in mid-2019. In the United States a potential launch of the product could occur in late Q2 or Q3, pending clearance from the FDA.

How it works: The ReStore promotes an improved gait with coordinated plantarflexion and dorsiflexion assistance to a patient's impaired foot and ankle. Power is transmitted from waist belt-mounted motors through cables to attachment points on the calf and an insole, which is placed in the patient's shoe. Sensors clipped to the patient's shoes detect motion and inform timing of the assistance. Using a handheld smartphone controller, a trained therapist is able to adjust assistance level, monitor key metrics such as session progress and gait symmetry, and record standard gait training assessments.

For more information about the ReStore system, please visit: www.rewalk.com

* *http://www.strokecenter.org/patients/about-stroke/stroke-statistics/*

About ReWalk Robotics Ltd.
ReWalk Robotics Ltd. develops, manufactures and markets wearable robotic exoskeletons for individuals with lower limb disabilities as a result of spinal cord injury or stroke. The Company's mission is to fundamentally change the quality of life for individuals with lower limb disability through the creation and development of market leading robotic technologies. Founded in 2001, ReWalk has headquarters in the United States, Israel and Germany. For more information on the ReWalk systems, please visit www.rewalk.com.

We currently hold a registered trademark in the United States and Israel for the mark "ReWalk." We currently hold a registered trademark in Europe and are in the process of registering the mark "ReStore" in the United States.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, Section 27A of the U.S. Securities Act of 1933, and Section 21E of the U.S. Securities Exchange Act of 1934. Such forward-looking statements may include projections regarding ReWalk's future performance and, in some cases, may be identified by words like "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "will," "should," "would," "seek" and similar terms or phrases. The forward-looking statements contained in this press release are based on management's current expectations, which are subject to uncertainty, risks and changes in circumstances that are difficult to predict and many of which are outside of ReWalk's control. Important factors that could cause ReWalk's actual results to differ materially from those indicated in the forward-looking statements include, among others: ReWalk's ability to secure capital from its equity and debt financings in light of limitations under its Form S-3, the price range of its ordinary shares and conditions in the financial markets, and the risk that such financings may dilute ReWalk's shareholders or restrict its business; ReWalk's ability to regain compliance with the continued listing requirements of the Nasdaq Capital Market and the risk that its ordinary shares will be delisted if it cannot do so; ReWalk's expectations regarding future growth, including its ability to increase sales in its existing geographic markets, and to expand to new markets and achieve its planned expense reductions; the conclusion of ReWalk's management and the opinion of ReWalk's auditors in that there are substantial doubts as to ReWalk's ability to continue as a going concern; ReWalk's ability to maintain and grow its reputation and the market acceptance of its products; ReWalk's ability to achieve reimbursement from third-party payors for its products; ReWalk's limited operating history and its ability to leverage our sales, marketing and training infrastructure; ReWalk's expectations as to its clinical research program and clinical results; ReWalk's ability to improve its products and develop new products; ReWalk's ability to repay its secured indebtedness; the outcome of ongoing shareholder class action litigation relating to ReWalk's initial public offering; ReWalk's compliance with medical device reporting regulations to report adverse events involving its products and the potential impact of such adverse events on ReWalk's ability to market and sell its products; ReWalk's ability to gain and maintain regulatory approvals; ReWalk's expectations as to the results of, and the Food and Drug Administration's potential regulatory developments with respect to, ReWalk's mandatory post-market 522 surveillance study and ReWalk's 510k submission for the ReStore for stroke patients; ReWalk's ability to maintain adequate protection of its intellectual property and to avoid violation of the intellectual property rights of others; the risk of a cybersecurity attack or breach of our IT systems significantly disrupting our business operations; the risk that the remaining Timwell Corporation Limited ("Timwell") issuances will fail to close and the China joint venture will not form, and the resulting effect on ReWalk's liquidity and financial condition; the risk of substantial dilution resulting from additional issuances, if any, to Timwell; the significant voting power and de facto voting control Timwell may acquire upon additional issuances, if any; ReWalk's ability to use effectively the proceeds of offerings of securities; ReWalk's ability to maintain relationships with existing customers and develop relationships with new customers; the impact of the market price of ReWalk's ordinary shares on the determination of whether ReWalk is a passive foreign investment company; and other factors discussed under the heading "Risk Factors" in ReWalk's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission (the "SEC") and other documents subsequently filed with or furnished to the SEC. Any forward-looking statement made in this press release speaks only as of the date hereof. Factors or events that could cause ReWalk's actual results to differ from the statements contained herein may emerge from time to time, and it is not possible for ReWalk to predict all of them. Except as required by law, ReWalk undertakes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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