ReWalk Launches Clinical Study for Its ReStore Soft Exo-Suit System

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Study of new powered soft exo-suit for stroke rehabilitation is intended to provide clinical data for upcoming FDA submission

MARLBOROUGH, Mass. and YOKNEAM ILIT, Israel, April 3, 2018 /PRNewswire-USNewswire/ -- ReWalk Robotics Ltd. (Nasdaq: RWLK) ("ReWalk" or the "Company"), a leading manufacturer of robotic exoskeletons, announced today the official launch of its clinical study of the ReStore soft exo-suit system (ReStore) for the rehabilitation of individuals with lower limb disability due to stroke. The first clinical study participant began using a ReStore last week at the Spaulding Rehabilitation Hospital in Boston, Massachusetts where the study is being led by a team of researchers from the Boston University College of Health and Rehabilitation Sciences: Sargent College. The study seeks to enroll 40 participants at five of the top rehabilitation hospitals in the U.S.

"Launching the clinical study is a crucial step forward in the effort to offer the ReStore as a commercial product for the rehabilitation of stroke survivors worldwide," said ReWalk CEO Larry Jasinski. "We are thrilled to continue our work with Spaulding—a renowned rehabilitation facility—and help patients access this cutting edge technology."

This first of its kind device, which was unveiled in 2017, is the second product line from ReWalk and represents the Company's next step in its efforts to develop new technologies designed to serve patients with various forms of lower limb disabilities.

The ReStore is designed to be a versatile, cost-effective gait therapy solution intended to allow therapists to deliver treatment with real time analytics and adjustability. It utilizes key features from structural exoskeleton designs without the size, structure and expense of current exoskeletons.

"The ReWalk ReStore is an innovative device with potential to alter how we treat gait impairments after stroke," said Lou Awad, PT, DPT, PhD, Assistant Professor, College of Health and Rehabilitation Sciences at Boston University, and Research Faculty Member at Spaulding's Stroke Research & Recovery Institute, as well as lead investigator for this study site. "We are excited to work with industry-leader ReWalk Robotics to kick off the first clinical trial of this next-generation rehabilitation technology."

How It Works: The ReStore transmits power to key joints of the legs with cable technologies, powered with software and mechanics that are similar to the technologies used in the ReWalk exoskeleton system for individuals with spinal cord injury. The cables are connected to fabric-based designs that attach to the legs and foot, thus lending the name "soft suit."

Anticipated delivery of a commercial ReStore soft suit is targeted for the first half of 2019. ReWalk plans to commercialize use of the ReStore system in Europe and the United States subject to receiving CE and FDA clearance, respectively, to market the device. The Company plans to apply for CE and FDA clearances once clinical and laboratory testing are completed.

For more information on the ReStore soft suit exoskeleton, please visit: www.rewalk.com.

About ReWalk Robotics Ltd.

ReWalk Robotics Ltd. develops, manufactures and markets wearable robotic exoskeletons for individuals with spinal cord injury. Our 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 U.S., Israel and Germany.

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 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 for the Company's financial statements for the fiscal year ended December 31, 2017, 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 ability to enroll participants in its clinical studies, including for the ReStore; ReWalk's expectations as to its clinical research program and clinical results; 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; the outcome of ongoing shareholder class action litigation relating to ReWalk's initial public offering; ReWalk's ability to repay its secured indebtedness; ReWalk's ability to improve its products and develop new products; ReWalk's ability to maintain adequate protection of its intellectual property and to avoid violation of the intellectual property rights of others; ReWalk's ability to gain and maintain regulatory approvals, including for the ReStore; 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 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; 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 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; the risk of substantial dilution resulting from the issuance to Timwell Corporation Limited ("Timwell"); the significant voting power and de facto voting control Timwell will acquire; the risk that the Timwell issuances will fail to close and the China joint venture will not form; and other factors discussed under the heading "Risk Factors" in ReWalk's Annual Report on Form 10-K for the year ended December 31, 2017 filed with the U.S. Securities and Exchange Commission and other documents subsequently filed with or furnished to the U.S. Securities and Exchange Commission. 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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