ReWalk Completes Critical Design Review Processes of Restore System for Move to Clinical Studies

October 16, 2017 12:30 PM EDT

Studies to focus on use with stroke patients

MARLBOROUGH, Mass. and YOKNEAM ILIT, Israel, Oct. 16, 2017 /PRNewswire/ -- ReWalk Robotics Ltd. (Nasdaq: RWLK) ("ReWalk") announced today completion of all internal processes to initiate clinical studies and the initial production of its "soft suit" exoskeleton design for stroke patients. Called "Restore," the new system is the first product in the company's expansion into new technologies that will serve mobility-challenged patient communities. This design is targeted to serve the stroke rehabilitation community.

This lightweight design of the Restore system was specifically configured for stroke survivors who face mobility issues. The system is designed to provide real-time adjustable walking assistance for stroke patients in a compact, light, modular soft exosuit structure. It utilizes some of the key features from structural exoskeleton designs in assisting rehabilitation, with the advancement of being able to achieve these goals without the size, structure and expense of current designs.

"Achieving successful laboratory testing and design review processes with the Restore system is a milestone that advances our efforts for commercialization," said ReWalk CEO Larry Jasinski. "The potential of these soft suit designs to expand the utilization of robotic technologies initially with stroke patients in rehab—and in the future for community use—is meaningful. Research into applications, such as multiple sclerosis anc Parkinson's Disease is the next horizon."

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 2018. ReWalk plans to commercialize use of the Restore system in Europe and the United States after receiving CE and FDA clearance, respectively, to market the device. The company intends to apply for CE and FDA clearances in mid-2018; CE and FDA clearance applications will be submitted as clinical and laboratory testing are completed in the coming months.

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. For more information on the ReWalk systems, please visit www.rewalk.com.

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, expand to new markets and achieve its planned expense reductions; the conclusion of ReWalk's management for the financial statements for the second quarter of 2017 and for fiscal 2016, and the opinion of ReWalk's auditors in their report on the Company's financial statements for fiscal 2016, 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 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; 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 its 2016 follow-on offering; 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 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; and other factors discussed under the heading "Risk Factors" in ReWalk's Annual Report on Form 10-K for the year ended December 31, 2016, as amended, 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.

View original content with multimedia:http://www.prnewswire.com/news-releases/rewalk-completes-critical-design-review-processes-of-restore-system-for-move-to-clinical-studies-300536820.html

SOURCE ReWalk Robotics Ltd.

Investor Contact: Lisa M. Wilson, President, In-Site Communications, Inc., T: 212-452-2793, E: lwilson@insitecony.com; Media Contact: Jennifer Wlach, T: 202-261-4000, E: media@rewalk.com