



ReWalk Announces Publication of ReStore Powered Exo-Suit Clinical Study Results

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Primary Study End Points of Device Safety and Feasibility Received Positive Results; Majority of Participants Experienced Clinically Meaningful Walking Speed Improvements

MARLBOROUGH, Mass., June 22, 2020 /PRNewswire/ -- ReWalk Robotics, Ltd. (Nasdaq: RWLK) ("ReWalk" or the "Company"), a manufacturer of robotic medical devices for individuals with lower limb disabilities, today announced the publication of the results of its multi-center clinical study of the ReStore Exo-Suit for rehabilitation of individuals with lower limb disability due to stroke. The study examined patient safety and explored functional walking outcomes in stroke survivors who completed a series of gait training sessions with the ReStore device.



This research was conducted primarily to support the Company's successful application to the U.S. Food and Drug Administration (FDA) for clearance of the ReStore Exo-Suit, which was issued in June 2019. The company also received CE Marking for the device in May 2019.

The findings of the study were published in the June issue of the [Journal of NeuroEngineering and Rehabilitation](#), and were the result of investigation by five leading U.S. rehabilitation institutions:

- 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; and
- Kessler Foundation in West Orange, NJ.

"This multi-site clinical trial of the safety and feasibility of the ReStore Exo-Suit is an important milestone in the field of rehabilitation technology," said Lou Awad, PT, DPT, PhD, Director of Boston University's Neuromotor Recovery Laboratory and the site investigator at Spaulding Rehabilitation Hospital for this study. "Physical therapists have historically relied on passive assistive devices to help patients with post-stroke hemiparesis walk safely. As an active assistive device, the ReStore soft robotic exo-suit offers new opportunities to retrain walking after stroke."

Thirty-six study participants with hemiplegia due to stroke each completed seven total study visits with the ReStore Exo-Suit. In addition to establishing device safety, which was the primary outcome for the study, several exploratory outcome measures were investigated, including a pre- and post-assessment of walking speeds, in which 64% of participants increased their unassisted walking speed by a clinically meaningful margin.

"We are thrilled to see the results from the ReStore clinical trial being published in a joint paper authored by the primary investigators from all five of our highly regarded study sites," said Kathleen O'Donnell, Director of Product Management and Strategy at ReWalk Robotics. "This work summarizes the first results from the largest soft exo-suit trial to date, and the positive findings in terms of safety and improved walking speeds showcase the potential of this technology to dramatically impact patient outcomes post stroke."

The first-of-its-kind ReStore Exo-Suit was unveiled in 2017 and was designed to be a versatile, cost-effective gait therapy solution to train for improved gait by providing coordinated plantarflexion and dorsiflexion assistance to a patient's impaired foot and ankle. Approximately 800,000 Americans suffer a stroke annually, and the majority will experience some level of gait impairment.

For more information on the ReStore Exo-Suit, please visit: rewalk.com.

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. ReWalk'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.

ReWalk® is a registered trademark of ReWalk Robotics Ltd. in Israel and the United States.

ReStore® is a registered trademark of ReWalk Robotics Ltd. in Europe and an allowed trademark 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 other statements that are not statements of historical fact 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 management's conclusion, and its independent registered public accounting firm's statement in its opinion relating to its consolidated financial statements for the fiscal year ended December 31, 2019, that there is a substantial doubt as to the Company's ability to continue as a going concern; the current COVID-19 pandemic has adversely affected and may continue to affect adversely business and results of operations; ReWalk's ability to have sufficient funds to meet certain future capital requirements, which could impair the Company's efforts to develop and commercialize existing and new products; ReWalk's ability to maintain 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 ability to establish a pathway to commercialize its products in China; 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 its sales, marketing and training infrastructure; ReWalk's expectations as to its clinical research program and clinical results; ReWalk's expectations regarding future growth, including its ability to increase sales in its existing geographic markets and expand to new markets; ReWalk's ability to obtain certain components of its products from third-party suppliers and its continued access to its product manufacturers; ReWalk's ability to repay its secured indebtedness; ReWalk's ability to improve its products and develop new products; the outcome of ongoing shareholder class action litigation relating to its initial public offering; ReWalk's compliance with medical device reporting regulations to report adverse events involving the Company's products, which could result in voluntary corrective actions or enforcement actions such as mandatory recalls, 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 its mandatory 522 postmarket surveillance study; 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 the Company's IT systems significantly disrupting its business operations; the impact of substantial sales of the Company's shares by certain shareholders on the market price of the Company's ordinary shares; ReWalk's ability to use effectively the proceeds of its offerings of securities; the risk of substantial dilution resulting from the periodic issuances of ReWalk's ordinary shares; the impact of the market price of the Company's ordinary shares on the determination of whether it 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 year ended December 31, 2019 and quarterly report on Form 10-Q for the quarter ended March 31, 2020 filed with 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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