



ReWalk Robotics Receives CE Mark for ReStore™ Exo-Suit Stroke Rehabilitation Device

May 29, 2019 12:30 PM EDT

Advent of the Soft Exo-Suit Generation expands assistive robotic therapy for stroke survivors

MARLBOROUGH, Mass. and YOKNEAM ILIT, Israel, May 29, 2019 /PRNewswire/ -- ReWalk Robotics, Ltd. (Nasdaq: RWLK) ("ReWalk" or the "Company"), a manufacturer of robotic medical devices for individuals with lower limb disabilities, today announced that the ReStore Exo-Suit for stroke rehabilitation has received CE marking, clearing it for sale to rehabilitation clinics in the European Union. This CE Mark is the first clearance of a soft exo-suit, a next generation medical device which can serve a larger and more diverse patient population facing mobility challenges.



ReStore's soft, garment-like design allows variability of movement which combines with first-of-its-kind plantarflexion propulsion 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.

"The ReStore revolutionizes post stroke gait training, providing key advantage to clinics, therapists and patients," said ReWalk CEO Larry Jasinski. "We developed this design through collaboration with the Wyss Institute at Harvard because of the unique opportunity to combine extensive depth of the supporting science and clinician involvement in designing the ideal system for stroke therapy in the clinic."

The company announced that ReStore will be priced significantly lower than the first generation of rigid exoskeleton technologies, and can be used to treat a broad range of stroke rehabilitation patients. ReWalk will offer direct purchase and third party leasing programs for the ReStore in the EU.

"The device's affordability and versatility make an attractive solution for a broader range of the rehabilitation market than previous technologies," Jasinski added. "Considering the high prevalence of stroke and the need for more effective and efficient clinical solutions, the marketplace for the ReStore is significant and holds immense promise for the continued innovation of care."

Stroke is a leading cause of disability which affects 17 million people worldwide each year.⁽¹⁾ As many as 80% of stroke survivors suffer from locomotor dysfunction, which is characterized as asymmetrical step length, slow velocity, and altered biomechanical alignment.⁽²⁾

ReStore is ReWalk's second marquee device, joining the ReWalk Personal 6.0—a robotic exoskeleton for home use by individuals with paralysis from a spinal cord injury. The expansion to soft exo-suits gives ReWalk a diverse offering of innovative technologies, and expands the company's impact to millions of patients worldwide. ReWalk intends to leverage its existing sales, training and service teams to commercialize the ReStore Exo-Suit. To date, ReWalk has placed nearly 550 exoskeletons in 26 countries and trained more than 270 rehabilitation clinics to conduct exoskeleton training worldwide.

"The soft suit technology is the first of a series of designs from the clinic for stroke therapy. It will also serve as a basis for a home therapy design that can be managed from the clinic, in addition to entering testing for treatment of Multiple Sclerosis and Parkinson's disease. The family of Soft-Exosuits are our foundation for revenue and financial growth of this company and for the industry as a whole," said Jasinski.

(1) https://www.stroke.org.uk/sites/default/files/the_burden_of_stroke_in_europe_-_challenges_for_policy_makers.pdf

(2) <https://synapse.koreamed.org/pdf/10.12786/bn.2017.10.e9>

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 U.S., 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.

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 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; the risk of decreased liquidity in the market for ReWalk's ordinary shares and a reduced market capitalization of the Company following the recently-effected reverse share split, and the risk of dilution following the recently-effected increase in authorized share capital; 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 its 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; ReWalk's ability to use effectively the proceeds of offerings of securities; ReWalk's ability to establish a pathway to commercialize its products in China; the risk of substantial dilution resulting from the periodic issuances of ReWalk's ordinary shares; 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.

 View original content to download multimedia: <http://www.prnewswire.com/news-releases/rewalk-robotics-receives-ce-mark-for-restore-exo-suit-stroke-rehabilitation-device-300857809.html>

SOURCE ReWalk Robotics

Investor Contact: Ori Gon, Chief Financial Officer, ReWalk Robotics Ltd., T: +972-4-9590123, E: investorrelations@rewalk.com; Media Contact: ReWalk Robotics, E: media@rewalk.com