FDA Awards Breakthrough Device Designation to the ReWalk ReBoot Soft Exo-Suit

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Soft exoskeleton device for stroke survivors will be for use at home and in the community to help with walking and mobility

MARLBOROUGH, Mass., Nov. 04, 2021 (GLOBE NEWSWIRE) -- ReWalk Robotics, Ltd. (Nasdaq: RWLK) ("ReWalk" or the "Company"), a leading global manufacturer of robotic medical devices for individuals with lower limb disabilities, today announced its ReBoot device has been granted designation as a Breakthrough Device by the Food and Drug Administration (FDA). The ReBoot is a lightweight, battery-powered orthotic exo-suit intended to assist ambulatory functions in individuals with reduced ankle function related to neurological injuries, such as stroke. The ReBoot is a customizable personalized device intended for home and community use. It is a sister product to the ReStore device, which received FDA clearance in 2019 for use in the rehabilitation setting.

“Breakthrough device designation from the FDA is a critical milestone for the ReBoot, as it provides a more streamlined review pathway that can get this uniquely innovative device to market faster,” said Larry Jasinski, CEO of ReWalk. “The ReBoot will give stroke survivors a device customizable for each individual user, giving them the opportunity for regular assistance at home and in the community.”

The ReBoot works in conjunction with the muscles of the affected leg to assist individuals not only with maintaining safe foot positioning but also with pushing off the ground, which means it may improve their gait. It may also:

- Facilitate muscle re-education, particularly of plantarflexor function;
- Prevent/retard disuse atrophy;
- Maintain or increase joint range of motion;
- Improve walking speed and endurance independent of the device; and
- Reduce incidence of falls due to poor foot positioning secondary to footdrop.

The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. It is available for devices and device-led combination products which are subject to review under a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request (“De Novo request”). The program is intended to help patients have more timely access to these medical devices by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, 510(k) clearance, and De Novo marketing authorization, consistent with the Agency’s mission to protect and promote public health. The Breakthrough Devices Program offers manufacturers such as ReWalk an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help us receive feedback from the FDA and identify areas of agreement in a timely way. The program also provides manufactures such as ReWalk prioritized review of their submission.

With this designation, ReWalk will now readily pursue the FDA approval pathway for the ReBoot. The company is finalizing the ReBoot’s design and development and will proceed to the clinical studies required for FDA clearance application.

For more information, please visit www.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 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 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: uncertainties associated with future clinical trials and the clinical development process, the product development process and FDA regulatory submission review and approval process; the adverse effect that the COVID-19 pandemic has had and may continue to have on the Company’s 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 maintain and grow its reputation and the market acceptance of its products; ReWalk's ability to achieve reimbursement from third-party payors, including CMS, 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 improve its products and develop new products; 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; ReWalk's ability to establish a pathway to commercialize its products in China; 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; the market and other conditions; and other factors discussed under the heading "Risk Factors" in ReWalk's annual report on Form 10-K for the year ended December 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.

ReWalk Media Relations:

Jennifer Wlach
E: media@rewalk.com

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

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