



FDA Issues Clearance for ReWalk 7 Exoskeleton

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Seventh Generation of Industry-Leading Exoskeleton Includes New and Enhanced Features for Individuals with Spinal Cord Injury

MARLBOROUGH, Mass. and YOKNEAM ILLIT, Israel, March 13, 2025 (GLOBE NEWSWIRE) -- Lifeward Ltd., (Nasdaq: LFWD) ("Lifeward" or the "Company"), a global leader in innovative medical technology to transform the lives of people with physical limitations or disabilities, announced today that the Company has received 510(k) FDA clearance for the newest generation of its personal exoskeleton device, the ReWalk 7. The seventh generation of the ReWalk, a wearable exoskeleton that allows individuals with spinal cord injury (SCI) to stand and walk again, includes a number of new features, as well as enhancements and upgrades.

"FDA clearance is a major milestone for our Company and for the industry," said Larry Jasinski, CEO of Lifeward. "For two decades, Lifeward has been committed to providing our users with the most advanced exoskeleton technology and expanding access to all those who can benefit from use of the device. With the ReWalk 7, we are able to deliver on that commitment, and will continue to look for opportunities to innovate and improve upon medical devices for the SCI community."

Clearance for the ReWalk 7 follows other major developments. In 2023, the FDA [cleared](#) the ReWalk 6.0 for use on stairs and curbs. In 2024, the Centers for Medicare & Medicaid Services (CMS) issued a national reimbursement [policy](#) for all beneficiaries that qualify for use of the device. The Company made history in 2014 when it received the nation's first FDA clearance for an exoskeleton medical device for individuals with SCI.

Lifeward will begin sales of the ReWalk 7 in the United States as soon as the product is available. For more information, please visit, [GoLifeward.com](https://golifeward.com)

About Lifeward

Lifeward designs, develops, and commercializes life-changing solutions that span the continuum of care in physical rehabilitation and recovery, delivering proven functional and health benefits in clinical settings as well as in the home and community. Our mission at Lifeward is to relentlessly drive innovation to change the lives of individuals with physical limitations or disabilities. We are committed to delivering groundbreaking solutions that empower individuals to do what they love. The Lifeward portfolio features innovative products including the ReWalk Exoskeleton, the AlterG Anti-Gravity System, the ReStore Exo-Suit, and the MyoCycle FES System. Founded in 2001, Lifeward has operations in the United States, Israel, and Germany.

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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 the Company'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 the Company's control. Important factors that could cause the Company'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 Company'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; the Company's ability to maintain and grow its reputation and the market acceptance of its products; the Company's ability to achieve reimbursement from third-party payors, including CMS, for its products; the Company's limited operating history and its ability to leverage its sales, marketing and training infrastructure; the Company's expectations as to its clinical research program and clinical results; the Company's expectations regarding future growth, including its ability to increase sales in its existing geographic markets and expand to new markets; the Company's ability to continue to operate as a going concern; the Company's ability to obtain certain components of its products from third-party suppliers and its continued access to its product manufacturers; the Company's ability to navigate any difficulties associated with moving production of its AlterG Anti-Gravity Systems to a contract manufacturer; the Company's ability to improve its products and develop new products; the Company'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 the Company's ability to market and sell its products; the Company's ability to gain and maintain regulatory approvals; the Company'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 Company's ability to use effectively the proceeds of its offerings of securities; and other factors discussed under the heading "Risk Factors" in the Company's annual report on Form 10-K, as amended, for the year ended December 31, 2024 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 the Company's actual results to differ from the statements contained herein may emerge from time to time, and it is not possible for the Company to predict all of them. Except as required by law, the Company 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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