

March 18, 2025



IR-MED CEO Issues Letter to Shareholders: Expanding Our Platform and Presenting New Clinical Data from Israel and the U.S.

Rosh Pina, Israel, March 18, 2025 (GLOBE NEWSWIRE) -- IR-MED Inc. ("IR-MED" or the "Company") (OTCQB: IRME), a developer of noninvasive, AI-driven spectrographic analysis technology addressing significant healthcare needs, is pleased to share the following shareholder update from its Chief Executive Officer, Mr. Ran Ziskind.

Dear Shareholders,

I am excited and honored to lead IR-MED as we continue to execute on value-driving milestones with our platform technology. We are actively expanding the usability studies of our first device, PressureSafe™, in the U.S., addressing a \$1.7 billion¹ market opportunity domestically and a \$2.9 billion market potential globally². With PressureSafe™ skin-agnostic Pressure Injury assessment, we believe PressureSafe™ has the potential to significantly reduce the harm caused by pressure injuries, offering a much-needed solution to a growing healthcare challenge.

Our commitment to a data-driven approach is evident in the usability studies we have already completed in Israel and are currently conducting in the U.S. Last month, our clinical and executive team had the privilege of demonstrating PressureSafe™ at the National Pressure Injury Advisory Panel ([NPIAP](#)) 2025 Conference, the leading U.S. conference for pressure injuries, held in the last week of February, 2025. During the conference our booth attracted significant interest from key opinion leaders, healthcare practitioners, scientists, and commercial partners, reinforcing the industry's enthusiasm for our innovative technology.

Key Clinical Study Updates

Two principal investigators presented compelling results from key studies:

1. Study Conducted at Clalit Medical Centers (Israel):
 - Final results from Beit Rivka Hospital and Rabin Medical Center, both part of Clalit, the world's second-largest Health Maintenance Organization (HMO).
 - This study assessed PressureSafe™'s Infrared Spectroscopy Scanner (IRSS) for assessment of Stage 1 pressure injuries (PI) and suspected deep tissue injuries (sDTI).
 - Findings from 924 scans showed a sensitivity of 89% and specificity of 90%, with

- no device-related adverse events across 1,475 scans.
 - The device enhanced assessment of pressure injuries before skin breakage, reduced reliance on subjective visual assessment, and contributed to a measurable reduction in pressure injuries.
2. Study Focused on Diverse Skin Tones (U.S.):
- Conducted at two Methodist hospitals in Texas to evaluate the effectiveness of Near-Infrared (NIR) Spectroscopy in overcoming pigmentation-related challenges.
 - Ongoing Phase 1 data from 294 scans demonstrated a 90% sensitivity rate, proving PressureSafe™'s reliability across diverse populations.
 - The use of the IRSS to assess the underlying tissue with a multi biomarker approach, provides a reliable quantitative approach to assist with clinical assessment by health care professionals.

Attending NPIAP 2025 further reinforced our belief in IR-MED's unique value proposition—we have both a groundbreaking technology and a receptive market ready for it. Moving forward, we are accelerating our usability studies in the U.S., paving the way for commercial milestones.

Expanding Our Product Pipeline: Introducing DiaSafe™

Beyond PressureSafe™, we are leveraging our platform technology to develop DiaSafe™—a decision-support device for diabetic foot ulcer (DFU) assessment. DFUs are a leading cause of amputations, resulting in severe patient suffering and placing a heavy financial burden on healthcare systems.³ DiaSafe™ aims to provide real-time, non-invasive optical readings of biomarkers to assess DFUs, enabling earlier and more effective intervention.

Key updates on DiaSafe™'s development:

- We have successfully completed the first year of development, backed by the Israel Innovation Authority (IIA) with a \$1 million budget (50% grant-funded).
- We have applied for a second IIA grant to support 2025 development.
- We are in advanced discussions with a healthcare provider to launch the first-in-human clinical trial.

Strategic Roadmap: Nasdaq Uplisting and Growth Plans

As part of our broader growth strategy, IR-MED is actively working toward uplisting to the Nasdaq Stock Exchange, a move that we believe will enhance shareholder value and expand our reach among institutional investors. We look forward to sharing additional updates on this initiative in the coming weeks and months.

We invite you to explore more about our technology, product pipeline, and clinical studies in our latest investor presentation and scientific posters [HERE](#).

Thank you for your continued support as we advance our mission to transform non-invasive skin assessment and improve patient outcomes

Sincerely,

Ran Ziskind

CEO, IR-MED Inc.

¹ Based on 2.4 million beds according to the American Hospital Association and the U.S. Centers for Disease Control. [U.S. Centers for Disease Control](#); [American Hospital Association](#);

² [Based on 8.3 million beds](#)

³ Transparency Markets and Research <https://www.transparencymarketresearch.com/diabetic-foot-ulcer-treatment-market.html>

About IR-MED

IR-MED Inc. is developing a cutting-edge infrared spectroscopy and AI analysis technology platform as a basis for point-of-care decision support devices. The infrared spectroscopy technology allows harmless and non-invasive gathering of bio-information from patient blood and tissue. Bioinformation is then analyzed using the company's AI based process to provide healthcare professionals with decision support in the assessment of various medical conditions.

PressureSafe, the company's first product based on this platform, is a handheld device designed to revolutionize the assessment of pressure injuries (PI) affecting skin and underlying tissue. Pressure Injury in the US alone accounts for \$26.8B in healthcare spending and results in 60,000 deaths annually. PressureSafe is expected to contribute to assessment of pressure injuries, regardless of patient skin tone. This will drive equitable healthcare and help reduce the toll and cost of pressure injuries (PI).

IR-MED holds patents protecting its innovation in noninvasive tissue assessment

PressureSafe is currently undergoing usability studies at multiple medical centers and is not yet available for commercial use.

Safe Harbor Statement / Forward-Looking Statements

statements included in this press release, which are not historical in nature, are forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. For example, IR-Med is using forward-looking statements when it discusses future usability studies, addressable market opportunities both domestically and globally, PressureSafe™'s potential to significantly reduce the harm caused by pressure injuries and address healthcare challenges, future commercial milestones, the development of the DiaSafe™ and its potential future benefits, receiving a second IIA grant to support 2025 development, the launch of a first-in-human clinical trial, its potential Nasdaq uplisting and potential for the uplisting to enhance shareholder value and expand the Company's reach among institutional investors. Statements relating to the future performance of IR-Med are subject to many factors including, but not limited to, the sufficiency of working capital and our ability to raise the capital needed to fund our development efforts, completion of the development and design of PressureSafe device, results of clinical/usability studies and trials, timing of product development, FDA approval/clearance of products in development, customer acceptance of our products in the market, the introduction of competitive products, the impact of any product liability or other

adverse litigation, commercialization and technological difficulties, and the other risks identified in our most recent annual report on Form 10-K/A filed on April 8, 2024 with the Securities and Exchange Commission. Such statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements. The forward-looking statements contained in this press release are made as of the date hereof, and we do not undertake any obligation to update any forward-looking statements, whether as a result of future events, new information, or otherwise.

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Attachment

- [IR-Med, Inc.](#)



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