

## IR-MED Chairman & Interim CEO Issues Letter to Shareholders

Rosh Pina, Israel, Aug. 21, 2023 (GLOBE NEWSWIRE) -- IR-MED Inc., ("IR-MED" or the "Company") (OTCQB:IRME), developer of a noninvasive Al-driven infrared spectrographic analysis technology platform to address significant healthcare needs, today issued the following update to shareholders from its Chairman & Interim Chief Executive Officer.

Dear Shareholders,

On behalf of the Board and entire the team at IR MED, we thank you for being a long term shareholder of our company. Your trust in our ability to execute on a multi-billion opportunity is appreciated and it is our hope that you will be well-rewarded.

As you may well be aware, we plan to uplist our common stock to a major exchange in the U.S., perhaps the Nasdaq or NYSE. We recently published our company's presentation which provides further detail on our technology, product pipeline, and markets. It can be found: <u>HERE</u>.

Important developments currently underway that are highlighted in the presentation include:

- We plan to list PressureSafe<sup>™</sup> with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2023, and pending regulatory approval, we expect commercial launch in the U.S. in the first half of 2024.
- PressureSafe addresses a \$600 million market opportunity<sup>1</sup> in the U.S. and \$2.9 billion globally<sup>2</sup>.
- A distributor in the U.S. is already in place and ready to launch in the first half of 2024, pending regulatory approval. The distributor will target hospitals, nursing homes, long term care facilities, and at-home care.
- The latest interim clinical data showed that PressureSafe identifies early-stage pressure injuries with 96% accuracy.
- In addition to the U.S., we plan to file for regulatory approval and launch PressureSafe in other markets including Canada and Europe.
- We are building a portfolio of products that address other significant markets where patients and healthcare payors can reap the benefits of our platform technology.

We invite you to follow our news closely as we launch PressureSafe to change the treatment paradigm for pressure injuries through early detection.

Sincerely,

Oded Bashan
Executive Chairman of the Board & Interim CEO
IR-MED. Inc

## **About IR-MED**

IR-MED Inc., is developing a noninvasive spectrographic analysis technology platform, allowing healthcare professions to detect, measure and monitor, in real time, different molecules in the blood, in human tissue, and in body fluids without invasive procedures. PressureSafe, the first product under development, is a handheld optical monitoring device that is being developed to support early detection of pressure injuries (PI) to the skin and underlying tissue, regardless of skin tone as it calibrates personally to each patient's skin.

IR-MED's technology is being developed to allow accurate readings of biomarkers in a non-invasive method, that may provide caregiver the optimal decision support-system in cases where uncertainties disturb physicians in their decision processes.

IR-MED holds patents protecting its technology and innovations in the noninvasive tissue analysis, and in the modeling and analysis of subcutaneous tissue.

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

## **Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities and Israeli securities laws. Statements that are not statements of historical fact may be deemed to be forward-looking statements. For example, the Company is using forward-looking statements in this press release when it discusses its expectancy to file for FDA approval in the fourth guarter of 2023, that the U.S. market launch is expected in the first half of 2024, the potential addressable market size and its plans to file for additional regulatory approval and launch in other markets, including Canada and Europe. Without limiting the generality of the foregoing, words such as "plan," "project," "potential," "seek," "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate" or "continue" are intended to identify forward-looking statements. Readers are cautioned that certain important factors may affect the Company's actual results and could cause such results to differ materially from any forward-looking statements that may be made in this press release. Statements relating to the future performance of IR-Med are subject to many factors including, but not limited to, the sufficiency or 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 preliminary clinical/useability studies and trials and confirmation by subsequent studies, replication of initial favorable product study results, timing of product development, FDA approval/clearance of products in development,

<sup>&</sup>lt;sup>1</sup>Based on 2.4 million beds according to the American Hospital Association and the U.S. Centers for Disease Control.

<sup>&</sup>lt;sup>2</sup> Based on 8.3 million beds.

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. The forward-looking statements contained or implied in this press release are subject to other risks and uncertainties, many of which are beyond the control of the Company, including those set forth in the Risk Factors section of the Company's Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 29, 2023 which is available on the SEC's website, <a href="https://www.sec.gov">www.sec.gov</a>. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release, except as required by law.

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Source: IR-Med, Inc.