

January 11, 2022



# IRME Letter to Shareholders

New York, N.Y., Jan. 11, 2022 (GLOBE NEWSWIRE) -- IR-Med, Inc. (OTCPINK: IRME).

*Our non-invasive monitoring technology enters the public eye – why I’m so excited for 2022.*

Dear new, old, and prospective IR-Med shareholders,

Welcome to IR-MED. After months of behind-the-scenes efforts, I’m excited to share with you what we’re working—and why I’m looking forward to **2022 as a transformative period for our team and our shareholders.**

As we look back and reflect on this past year, I am proud of our team and of the progress we have made during the Covid-19 pandemic related uncertainty across all corners of the globe. While the pandemic has presented, and continues to present, many challenges that are out of our control, we remain resolute and focused on that which is within our control, including our operational, clinical and regulatory work. We continue to make progress on all fronts and firmly believe that we are on the right path towards meaningful, value-adding milestones and transformational catalysts.

IR-MED aims to become the gold standard in the detection and monitoring of medical conditions by developing and commercializing non-invasive, high usability, Real Time, Optical diagnostic devices based on the combination of Infra-Red (IR) Optical Spectrography and Artificial Intelligence (AI) technologies. Our non-invasive, user-friendly medical devices (which are currently in various stages of development) are being designed to allow for **the early detection of myriad medical conditions**. Put simply, our devices are being designed to detect and monitor molecules in tissue and blood without having to take a single drop of blood from the patient and providing the physician/care giver a Decision Support System (DSS).

Our initial device incorporating our proprietary technologies targets incipient Pressure Injuries (PI) Sub-dermal before they are visible, a major challenge for care providers globally. Failure to identify and treat PIs is potentially fatal, with an estimated 60,000 mortalities in the US each year (Padula and Delarmente, Int. Wound J., 2019), and treatment is both time-consuming and costly. Currently, PI can best be treated only after appearing on the patient’s skin: a sore or wound that requires considerable care. Our proprietary, user-friendly, non-invasive and real-time monitoring device – PressureSafe, is designed to provide a Decision Support System and is expected to allow for preemptive detection of PI. The device is at advanced stage of development to deal effectively with the main diagnostic problems of identifying and differentiating between Deep Tissue PI (before it becomes visible) and Stage 1 PI by providing decision support system allowing early and accurate detection. Accurate detection of PI before the Stage I phase may save lives, patient pain, stress, and substantial expense to care providers and patients alike. Our optical

scanner is designed to detect Sub-dermal injuries, under the skin surface, and is equally effective regardless of skin tone, while calibrating to each patient's skin, i.e. a **personalized medical device**. PI presents a tremendous market opportunity for our company, and we believe 2022 is our budding year.

We expect the following milestones to be achieved during 2022:

- **Proof of Concept Results H1 2022** - In early 2022 we are planning to begin a useability study to show proof of concept with our PressureSafe device. In December 2021 we received an IRB-Helsinki Committee approval from Bet Rivka Medical Center, part of Rabin Medical Center in Israel. We expect results quickly and are highly optimistic about outcomes given clinician experience with this device to date.
- **File For FDA Clearance - H1 2022** - We plan to file for 510(k) clearance with the United States FDA in the first half of 2022.
- **Production capabilities - Q4 2022** – By the end of the year, subject to FDA clearance, we are planning to start production activities in order to be ready to launch into the lucrative US PI market.
- **JV and BD Efforts 2022** - We have begun business development efforts to identify nursing homes, home care organizations, and JV or licensing opportunities with both potential customers and partners.
- **Corporate and Financial Development** – We concurrently initiated a strategy to upgrade our position in the public markets and increase IR-Med visibility to a wider range of investors and have submitted application materials to OTC Markets Group to up list to the OTCQB market tier. The OTCQB Venture Market is designed for developing and entrepreneurial companies. Companies must be current in their financial reporting and undergo an annual verification and management certification process, including meeting a minimum bid price and other financial conditions. With more compliance and quality standards, the OTCQB provides investors improved visibility to enhance trading decisions. The listing of IR-Med's common stock on the OTCQB remains subject to the approval of the OTCQB and the satisfaction of applicable listing requirements. IR-Med already meets one of OTCQB Venture Market compliance requirements by having audited annual financials prepared in accordance with U.S. GAAP by a PCAOB auditor and maintains a Verified Company Profile at [OTCMarkets.com](https://OTCMarkets.com).

In addition to the *PressureSafe* device, we are concurrently developing an advanced otoscope called Nobiotics to provide physicians with immediate information as to whether an ear infection is viral or bacterial in nature. Over 20 million children in the U.S. and E.U. are affected by ear infections each year (Suaya et al., Vaccine, 2018) and diagnosing a causal pathogen behind the eardrum is nearly impossible. Our device will work through IR-spectrographic analysis, like PressureSafe, to decision support system for ideal treatment for young children.

Reflecting on the considerable work that's gone into our technology to date, I'm thrilled that we're now public facing. We thank you for your continued support and interest. Looking forward,

Dr. Rom Eliaz, Chief Executive Officer

### **About IR-Med**

IR-Med Inc., is developing non-invasive spectrographic analysis technology, allowing healthcare professions to detect and measure different molecules in the blood and in human tissue in real-time without any invasive procedures. 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 and which calibrated personally to each patient's skin, primarily caused by prolonged pressure associated with bed confinement. IR-med skin-device-interphase development of personalized medical devices allows high accuracy readings from the human body in a non-invasive method, that may provide caregiver the optimal decision support-system in cases where uncertainties disturb physicians in their decision processes.

Currently, IR-med holds patents protecting its innovation in the noninvasive tissue analysis, and in the modeling and analysis of subcutaneous tissue. The company is in preliminary process of examining the filing of additional patents applications.

### **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. 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, 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, successful up-list to OTCQB, and the other risks identified in the S-1 resale registration statement filed 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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