

September 16, 2025



IR-MED Investor Update Letter - Sept-2025

Rosh Pina, Israel--(Newsfile Corp. - September 16, 2025) [-IR-MED Inc.](#) (OTCQB: IRME) ("IR-MED" or the "Company"), a developer of non-invasive artificial intelligence (AI)-powered spectrographic technology to address critical healthcare challenges, today published an investor update.

Dear Valued Investors,

As we enter September 2025, in addition to Q2 financial reports and to the 8K recently published, I find it appropriate to update you on the developments within our Company. As you will see from the information below, the Company has achieved meaningful milestones that could bring it closer to the start of commercial operations. In order to move from potential to realization, we need your continued support. Please note that based on the Company's current expected level of operating expenditures, the Company's cash resources as of June 30, 2025, the Company's ability to undertake the operational and strategic actions described in this update is contingent upon securing additional funding. The Company's management is making active efforts through various financing avenues to obtain the required funding.

Product and Clinical Aspects

PressureSafe™

- IR-MED's PressureSafe™ and its Disposable Tip are now FDA-listed, enabling commercial entry into the U.S.
- PressureSafe™ has proven its effectiveness in multi clinical trials in diverse patient populations with different skin tones.
- The Company's technology addresses longstanding disparities in skin assessment, particularly in patients with darker skin tones that suffer more than twice as much as those with lighter skin.

DiaSafe™

- The Company received a \$500K grant plan for DiaSafe™ that was awarded by the Israel Innovation Authority (the "IIA").
- The IIA grant funding will support clinical advancement of DiaSafe™, an AI-powered diagnostic device for diabetic foot ulcers. The first in human clinical study is planned to commence soon in a leading medical center in Northern Israel.
- **DiaSafe™ with its complementary AI-driven solutions positions IR-MED to**

address additional large wound care markets among high-risk diabetic patients.

Usability Study at Methodist San-Antonio Texas

- Since the Company views the U.S. market as a key strategic priority, it is important for us to demonstrate clinical results within the U.S. and not rely solely on data from the clinical study conducted in Israel. U.S. healthcare providers place significant importance on this distinction. Our first active site in the U.S. is HCA Methodist Healthcare, the largest healthcare provider in South Texas, operating 10 hospitals and over 25 outpatient clinics in the San Antonio area.
- The trial is a 2-stage trial, the first stage results achieved 94% sensitivity with no safety concerns.
 - 786 scans across 163 anatomical sites, 61% from patients with darker skin tones.
- Few weeks ago, we have initiated the second stage of the trial, we anticipate this stage will take up-to 6 months.

Principal Investigator **Dr. Mary Lee Potter, PhD, MBA, RN, CWOCN**, stated: "PressureSafe represents a promising advancement in pressure injury prevention, offering clinicians a rapid, objective tool to assess tissue risk, especially in patients with dark skin tones. These interim findings validate the device's clinical potential to improve equity and patient outcomes. To further highlight the impact of this research, Dr. Potter has been invited to provide a podium presentation at the 2025 ANCC Magnet/ANE Research Symposium, the largest annual gathering of nursing professionals in the U.S., to be held on October 7th, 2025, in Atlanta, GA, where she will showcase PressureSafe's role in addressing disparities in pressure injury assessment."

Additional Usability Trial at a Major East Coast Hospital

Following over 12 months of due diligence and preparation, we are now in the advanced stages of Institutional Review Board ("IRB") submission, as well as handling the associated legal and financial documentation.

These clinical milestones not only validate the strong performance of PressureSafe™ in real-world U.S. healthcare settings but also pave the way for broader adoption by frontline caregivers—positioning the device as a transformative tool in equitable and effective pressure injury prevention., we believe that gaining entry into two of the most prominent hospital networks in the U.S. is not only a significant honor, but also a major commercial opportunity that strengthens our foothold in the largest healthcare market in the world.

Pilot Studies and Transition to Initial Commercial Production

We are aiming to secure **several pilot programs in the first half of 2026** in several health care settings across the U.S., which would serve as the cornerstone for our **initial go-to-market strategy** and will help shape our product's adoption path.

Fundraising

As we approach the final stage towards commercialization phase, we believe it is reasonable

to expect that within the coming years, sales could become meaningful. In parallel, we are seeing growing interest from highly respected medical care networks and players in the industry. Collaborations with such entities—should they materialize—could further support our growth and contribute to our long-term value.

With regard to the company's strategic plan to uplist to a major stock exchange, such as NASDAQ or the New York Stock Exchange, NYSE American (NYSE), we wish to emphasize that this goal remains a top strategic priority. We are actively working toward achieving it, as we believe that uplisting will significantly enhance the company's valuation, improve share liquidity, and broaden our investor base.

However, we recognize that current conditions—both in terms of operational readiness and financial positioning—are not yet optimal for such a move. We therefore plan to pursue the uplisting after additional capital raise on the OTC market, as well as upon reaching key product development and clinical milestones anticipated in the coming months. These steps will better position the company for a successful uplisting.

As part of our preparations, we have engaged with a leading investment bank that will support and guide us through the near-term fundraising as well as the future uplisting process. We will continue to keep you informed as this effort progresses.

IR-MED's current market valuation is significantly misaligned with its actual stage and potential. While the reasons for this gap can be debated, the **need to correct this misalignment is clear and urgent**. We are committed to taking a **more active and strategic approach** to investor and public relations. As a publicly traded company, **visibility, communication, and consistent market engagement** are essential. We recognize the importance of **investing in efforts that will raise awareness and better position the Company in the eyes of the market**.

In Summary

We are navigating a demanding and pivotal period, both operationally and strategically. Despite the challenges, I remain confident and optimistic about our path forward. I sincerely hope that our existing investors, along with new collaborations, will share this optimism and continue to support us in driving the Company toward its goals.

Ran Ziskind,
Chief Executive Officer

About IR-MED

IR-MED Inc. is developing a cutting-edge infrared spectroscopy and AI analysis platform technology 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 skin 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 platform product, 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 [\\$26.8 billion](#) in healthcare spending and results

in [60,000](#) deaths annually. PressureSafe offers healthcare professionals a real-time evaluation of skin, regardless of patient skin tone. The potential assessment of pressure injuries using PressureSafe holds significant promise in addressing this widespread healthcare challenge and potentially reducing its burden worldwide.

IR-MED holds patents protecting its innovation in non-invasive 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 the Company's ability to initiate clinical trials in the first half of 2026 pending final approvals; the Company's ability to secure several pilot programs in the first half of 2026 in several health care settings across U.S.; that within the coming years, sales could become meaningful; that future collaborations could further support the Company's growth and contribute to its long-term value; future uplisting to a national exchange; future capital raises; reaching key product development and clinical milestones anticipated in the coming months. Statements relating to the future performance of IR-Med are subject to many factors including, but not limited to, the accuracy of the Company's estimates regarding expenses, future revenues, uses of cash, capital requirements and the need for additional financing; the initiation, cost, timing, progress and results of our development activities, usability studies, preclinical studies and any clinical trials that it may be required to undertake; the timing of and the Company's ability to obtain and maintain regulatory approval of our existing product candidates, any product candidates that it may develop, and any related restrictions and/or limitations; the company's plans to research, develop and commercialize its current and future product candidates; the Company's ability to attract collaborators with development, regulatory and commercialization expertise; the company's ability to obtain and maintain intellectual property protection for its product candidates; the Company's ability to successfully commercialize its product candidates; the size and growth of the markets for its product candidates and its ability to serve those markets; the rate and degree of market acceptance of any future products; the success of competing devices that are or may become available; regulatory developments in the United States and other countries; the performance of its third-party suppliers and manufacturers and its ability to obtain alternative sources of raw materials; the impact of global inflationary pressures; its ability to obtain additional financing; use of the proceeds from its securities offerings; any restrictions on its ability to use its net operating loss carry-forwards; the impact of Israel's multi-front war on its results, including potential economic restrictions imposed on and political and military instability in Israel; its ability to attract and retain key personnel, and the other risks identified in our most recent annual report on Form 10-K filed on April 4, 2025 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.

Contact:
Hanover International, Inc.
Kathy Cusumano, President
Contact@ir-medical.com



To view the source version of this press release, please visit
<https://www.newsfilecorp.com/release/266250>

SOURCE IR-MED, Inc.