



# SENSING THE INVISIBLE

**NON-INVASIVE BIOMARKER ANALYSIS OF BLOOD AND TISSUE AT THE POINT OF CARE**  
**Addressing multi billion-dollar diagnostics and monitoring market**

**May 2024**

**OTCQB: IRME**

**[www.ir-medical.com](http://www.ir-medical.com)**

# Forward-looking Statement

This presentation of IR-MED Inc. (the “Company”) contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities law. Words such as “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” and similar expressions or variations of such words are intended to identify forward-looking statements. For example, the Company is using forward- looking statements when it discusses its vision, the potential of its product, its potential future products and strategy, the market potential of its product, the commercialization of its products, the expected timeline of regulatory submissions and approvals of its products and its future growth. Forward-looking statements are not historical facts, and are based upon management’s current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management’s expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed or indicated by the forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the forward-looking statements. For a more detailed description of the risks and uncertainties affecting the Company, the reference is made to the Company’s reports filed from time to time with the Securities and Exchange Commission (the “SEC”), including, but not limited to, the risks detailed in the Company’s Annual Report on Form 10-K/A for the year ended December 31, 2023, filed with the SEC on April 8, 2024, and in subsequent filings made by the Company with the SEC. Forward-looking statements speak only as of the date the statements are made. The Company assumes no obligation to update forward-looking statements to reflect actual results, subsequent events or circumstances, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws.



# Overview

IR-MED's patented spectrographic and AI-based technology platform brings biomarker profiling to point of care devices, providing healthcare professionals with non-invasive, skin tone agnostic, real-time data-driven analysis of blood and tissue to identify medical conditions.

*Winner of Two Israel  
Innovation Authority Grants*



## CHANGING TREATMENT PARADIGMS & ECONOMICS IN MULTI-BILLION DOLLAR MARKETS<sup>1</sup>



1) [Markets and Markets](#) 2) [NPIAP Fact Sheet](#)

Ticker: IRME | 3

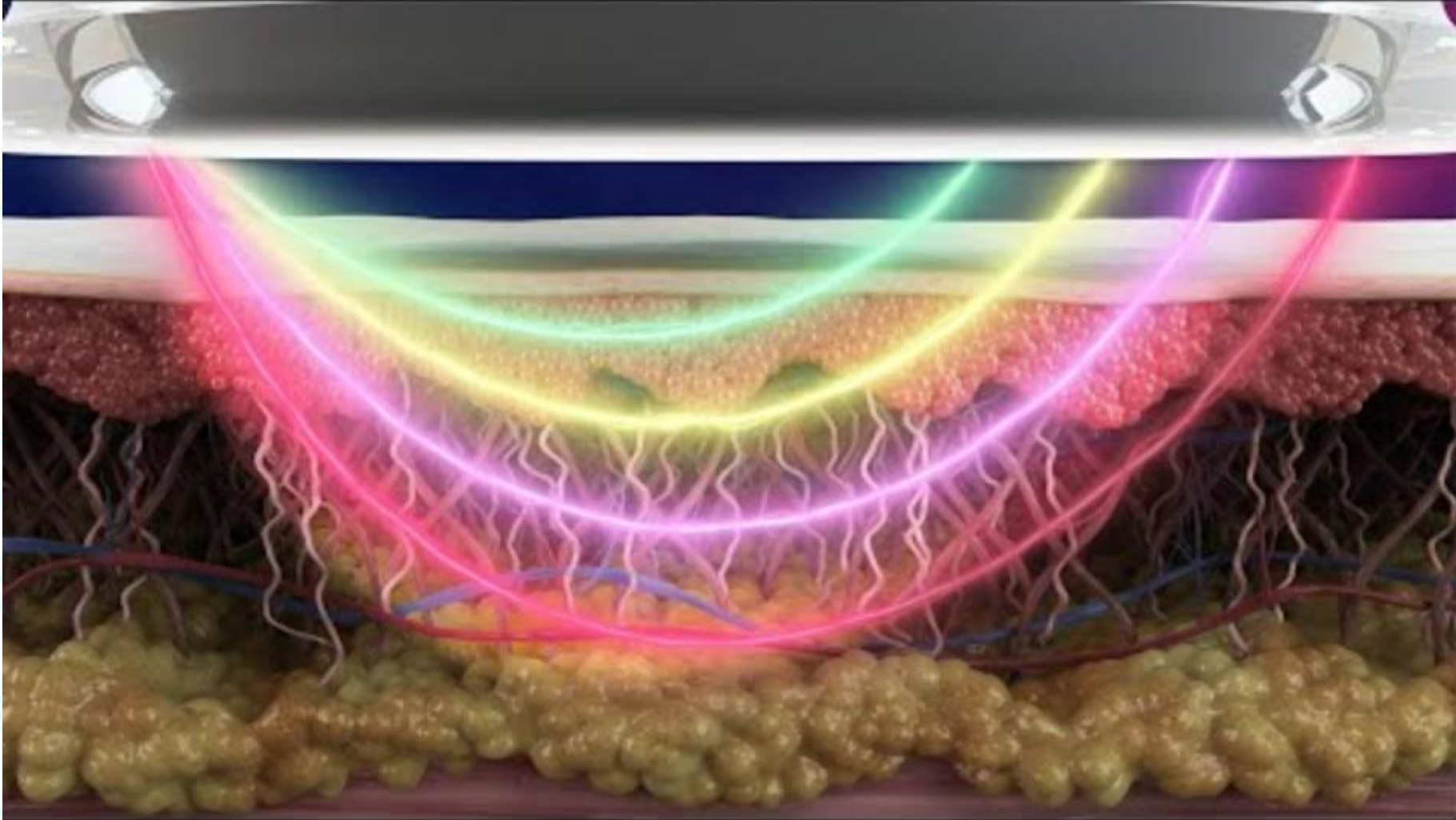


**PressureSafe™, IR-MED's first product, is a handheld device with AI-based decision support that identifies early-stage pressure injuries with 92% accuracy\*, providing a novel solution to a \$26 billion<sup>2</sup> problem and driving healthcare equality for people of all skin tones.**



*\*From a usability study conducted at two leading hospitals in Israel demonstrating 92% sensitivity based on 924 scans on 154 body locations on 38 patients.*

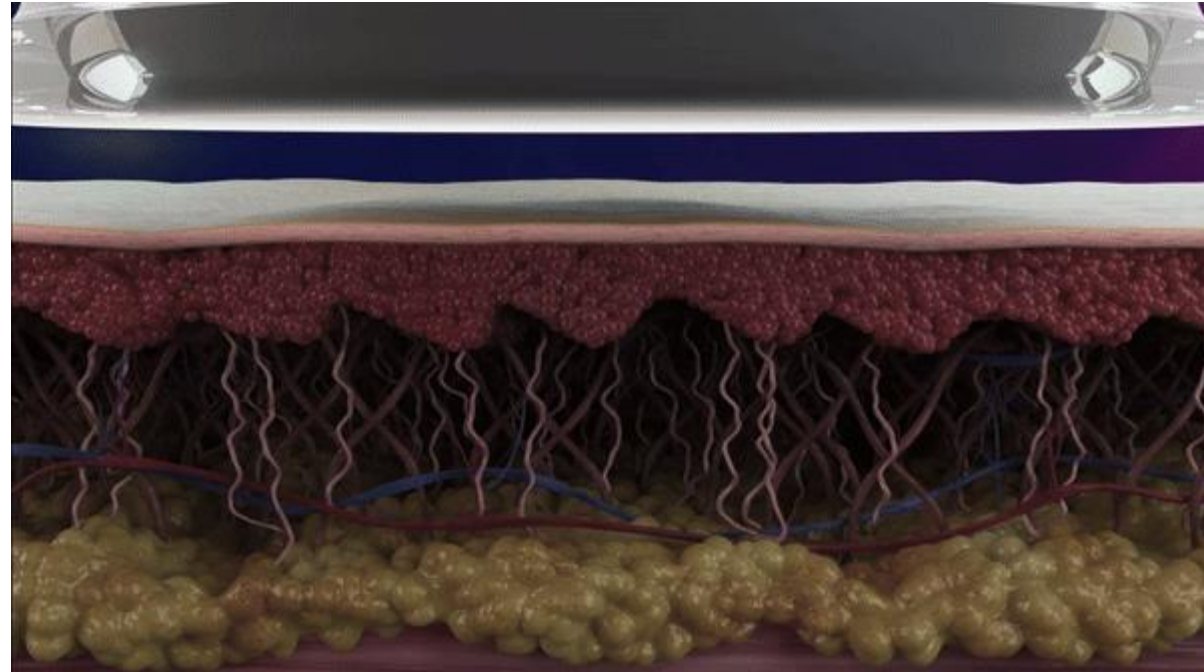
# Sensing the Invisible





# HOW IT WORKS

- 1) Biomarker profiles are identified for each medical condition.
- 2) A handheld device that contains miniaturized electronics and passive sensors sends and detects visible light and infrared light.
- 3) The light is used to acquire biological information by assessing light reflected from different layers under the skin's surface.
- 4) Sensor results are classified and analyzed by a cloud-based AI-system at the point of care into the predefined conditions.



# AI-Driven Point of Care Decisions



## PressureSafe™

Decision support device for detection of pressure injuries

**\$2.9 billion global total addressable market<sup>1</sup>**

### Future Tissue/Skin Indications:

Monitoring open wounds, burns etc.\*

Tissue / Skin Health



## DiaSafe™ \*

Decision support device for diabetic foot ulcer detection\*

**\$10.5 billion global diabetic foot ulcers treatment market<sup>2</sup>**

Diabetic Foot Ulcer

## Future indications



## NoBiotics\*

Detection of the source of ear infections: viral vs. bacterial

Ear Inflammation



## Therapeutic Drug Monitoring\*

Non-invasive measurement and monitoring of drug levels in the blood

Non-Invasive Drug Monitor

## Products

## Indications

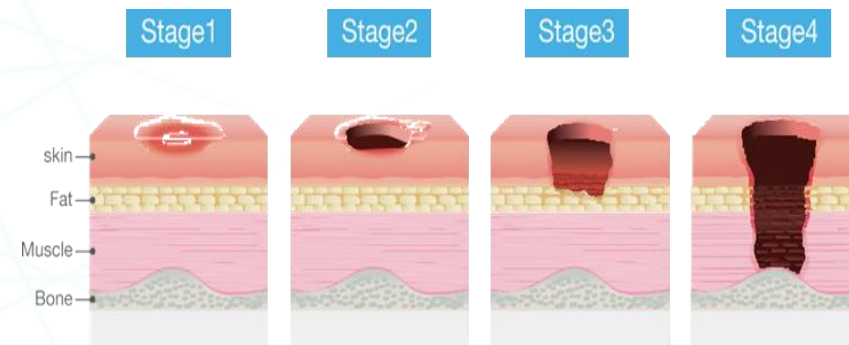
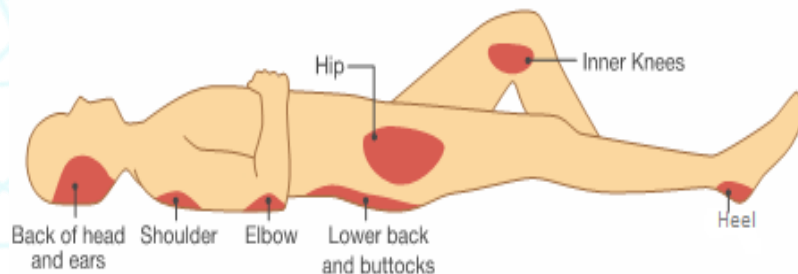
## Platform Technology

**Real-Time | Non-Invasive | Optical Monitoring & Detection of Biomarkers & Artificial Intelligence Classification**



# Pressure Injuries

- Pressure injuries are skin conditions caused by mechanically-induced ischemia.
- Most pressure injuries occur over bony prominences (such as heels and sacrum) where there is compressed or diminished tissue. External pressure further hampers regular blood supply to the tissue.
- Currently, visual inspection is used to detect and classify pressure injuries according to depth, width, degree of tissue loss and presence of granulated tissue.
- Stage 1 pressure injuries present in intact skin surface with non-blanchable redness of a localized area. Early detection is particularly challenging in darker-toned pigmented skin.
- **Research shows that people with dark skin tones suffer from pressure injuries more than twice as much as those with lighter skin.**



# Tremendous Healthcare Burden in the U.S.

## Pressure Injury Deaths Compared to Other Major Causes Annually

Drug overdose	63,600
<b>Pressure injuries</b>	<b>60,000</b>
Influenza	56,000
Suicide	44,000

- 60,000 patients die every year as a direct result of pressure injuries.
- Second most common claim for lawsuits after wrongful death.
- \$26.8 billion - total cost of acute care attributable to hospital-acquired pressure injuries.
- 2.5 million patients per year develop a pressure injury.
- Patient care cost per pressure injury up to \$151,700.
- One of the five most common harms experienced by patients.
- Hospital acquired pressure injury rates are increasing while all other hospital acquired conditions are decreasing.
- Pressure injuries occur across the healthcare spectrum.
- 10% of patients in acute care get pressure injuries.

*U.S. Centers for Medicare and Medicaid Services reduced the reimbursement related to hospital-acquired pressure injuries. Hospitals pay more of the financial burden of these harms.*



# Features & Benefits

PressureSafe™



# PressureSafe™

Fast AI-based decision support system with high accuracy

## Advantages

- User-friendly, non-invasive, handheld device for real-time monitoring and **preemptive** detection of Stage 1 pressure injury and deep tissue injury.
- **Effective regardless of skin tone:** calibration to patient skin tone and tissue parameters.
- Device is gently touched to specific points of skin that are at high risk to develop pressure injuries such as heels and sacrum.
- Integrates with electronic medical and hospital records.
- Designed for easy expansion into a comprehensive wound management system.
- Designed to improve healthcare economics through healthcare worker efficiency and reduced harm of pressure injuries.



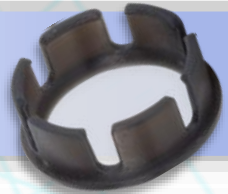


# Pressure Injury U.S. Market Economics

**PressureSafe™ scanner listed with U.S. FDA\***

**Planned to be launched during 2024**

**Recurring Revenues:**



Pay Per Use based on disposable tip used per patient test

Device sales/lease



SaaS for cloud-based data



**\$600 M opportunity in U.S. upon product launch<sup>2</sup>**

**CMS reimbursement code recently established —expected to accelerate market adoption**

## **Nursing Homes:**

15,600 with 1.7 million beds, typically occupied by 1.3 million patients<sup>1</sup>

## **Hospitals:**

Approximately 6,000 hospitals with many departments having patients at risk of developing pressure injuries, e.g. ICU, admission and others.

## **Home-Care:**

Millions of patients.

**Estimated total addressable market:**  
**200+ million tests annually,**  
**average 2 tests per week.**



\* PressureSafe™ scanner and disposable pack have been registered and listed with U.S. FDA as a Class I device, which is exempt from a 510(k) premarket submission, however it is not Good Manufacturing Practice exempt from quality system requirements.

1) U.S. Centers for Disease Control

2) Based on 2.4 million beds according to the American Hospital Association and the U.S. Centers for Disease Control.

# Clinical Studies at Top Hospitals

- ✓ Methodist Healthcare in the U.S.
- ✓ Clalit in Israel



## Usability Study: Israel

Conducted at two hospitals owned by Clalit, world's 2<sup>nd</sup> largest HMO and Israel's largest, with 4 million members, 14 medical centers, 1,500 clinics.

Beit Rivka - Geriatric Medical Center, Israel  
Rabin Medical Center - Leading General Hospital, Israel

*Results presented at National Pressure Injury Advisory Panel (NPIAP) 2024 Annual Conference in Texas*

- ✓ **924 scans on 154 body locations on 38 patients**
- ✓ **92% sensitivity**
- ✓ **88% specificity**
- ✓ **No safety signals identified on 1,493 scans on 66 patients**

### Indication

**Decision Support Device for Detection of Pressure Injuries**

### Regulatory Status

**Listed with U.S. FDA** as a Class I device that is exempt from 510(k) filing  
**EU, UK, and Canada:** Submissions are planned.

## Usability Study: U.S.

Study planned to launch during 2024 at Methodist Healthcare System of San Antonio

A network of 85 hospitals  
11,000 employees with 2,700 physicians.  
Most respected provider in its region.

*Study to address challenge of early detection in people with dark skin tones.*

*50% of patients recruited will have dark skin.*



# DiaSafe™

## Fast AI-based decision support system for diabetic foot ulcer (DFU) detection

- Israel Innovation Authority examined IR-MED's platform technology and awarded a **second grant** for diabetic foot ulcers, following a prior grant for pressure injuries.
- Early detection can **reduce healthcare costs, save limbs, and save lives.**
  - More cost effective to manage in initial stages.<sup>1</sup>
  - Detecting and treating early DFU can significantly improve quality of life by reducing pain and mobility issues.<sup>2</sup>
  - Early intervention can reduce death rate associated with diabetic foot complications.<sup>3</sup>
- Diabetic foot ulcers are the most common cause of amputation and a \$10.5 billion global treatment market expected to grow to \$17.7 billion by 2031.<sup>4</sup>
- DiaSafe™ is being developed to provide safe, real-time optical readings of biomarkers to detect the presence of diabetic foot ulcers with high accuracy.



1) [ClinicoEconomics and Outcomes Research](#) 2) [Frontiers in Endochronology](#) 3) [Journal of Public Health Research](#) 4) [Transparency Markets and Research](#)



# Upcoming Milestones\*\*

Uplist to Nasdaq/NYSE



**DiaSafe™:** 2024/5—Key developments expected in production and clinical studies

**NoBiotics:** 2025—Key developments expected in biomarker profiles

**Therapeutic Drug Monitoring:** 2026—Developments expected with regards to drug candidates and potential partnerships

Timelines are subject to change. There are inherent risks and variability regarding the overall regulatory process. Approval by the FDA and European Medicines Agency may not be granted, or such regulators may have input and required edits with respect to the intended regulatory submissions.



\*Pending regulatory approvals.

\*\* On February 28, 2024, following financial difficulties our Board of Directors resolved that the Company's operations will be limited only to critical actions in order to save funds. Accordingly, the upcoming milestones for our product candidates' development and commercialization plans are currently on hold and are subject to us being able to raise additional funds to support our operations and to further develop and commercialize our products, which are in various stages of design and development.



# Equity Summary

**Fully reporting company listed on OTCQB**

**Ticker: IRME**

(as of May 13, 2024)

**Price Per Share: Approximately \$.90**

**Market Cap: \$63 M**

**Shares Outstanding: Approximately 70 M**

**Held by Insiders: 50%**



# Leadership Team



**Oded Bashan**  
*Executive Chairman*

Over 40 years of experience in managing, building and running technology companies. Founder & CEO of OTI, a NASDAQ traded global technology leader with more than 250 employees.



**Ronnie Klein**  
*Interim CEO & CTO*

A medical device and biotech expert with a strong clinical background and target driven leader. 25 years of experience in taking good ideas into medical products. Over 30 patent submissions.



**Yaniv Cohen, PhD**  
*Co-Founder & CSO*

A skilled scientist and entrepreneur, with years of experience leading R&D development for medical devices companies. His fields of expertise include electro-optics, infrared spectroscopy and medical devices using infrared light.



**Sharon Levkoviz**  
*CFO*

Served as regional manager of Achdut Israel Ltd., Chief Controller at OTI Global, Chairman of Finance and Human Resource Committee at Ohalo College and as a Director at the development company of Katzrin.



**Aharon Binur**  
*CDO*

Electronics engineer with extensive experience in multidisciplinary technological management, including software, hardware and mechanics, development of final systems to commercialization. Served as VP of R&D and Products at OTI, CTO and VP of R&D at Lehavot.





# Thank You

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