UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): **September 17, 2024**

IR-MED, INC.

Nevada	**000-56492**	**84-4516398**
(State or Other Jurisdiction Of incorporation)	(commission File Number)	(IRS Employer Identification Number)

ZHR Industrial Zone Rosh Pina Israel	**1231400**
(Address of Principal Executive Offices)	(Zip Code)

+ 972-4-655-5054
(Registrant's telephone number, including area code)

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
N/A	N/A	N/A

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 17, 2024, IR-Med, Inc. posted to its website an updated investor presentation, a copy of which is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1	Investor presentation (furnished herewith)
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IR-Med, Inc.

By: */s/ Sharon Levkoviz*

Name: Sharon Levkoviz
Title: Chief Financial Officer

Date: September 17, 2024

SENSING THE INVISIBLE

NON-INVASIVE BIOMARKER ANALYSIS OF BLOOD AND TISSUE AT THE POINT OF CARE

Addressing multi billion-dollar diagnostics and monitoring market

September 2024

OTCQB: IRME

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, and the sales strategy and revenue streams estimations. 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.

Early detection of medical conditions can save lives and improve healthcare economics.

CHANGING TREATMENT PARADIGMS & ECONOMICS IN MULTI-BILLION DOLLAR MARKETS[1]

[1]Markets and Markets [2] NPIAP Fact Sheet

PressureSafe™

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[2] 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.*

Award Winning Disruptive Technology Born in Israel

Winner of Two Israel Innovation Authority (IIA) Grants

Most Innovative Non-Invasive Diagnostics Technology Developer 2023

2023 corporatevision Future of better business Small Business Awards

The Netty Awards AN OFFICIAL NETTY WINNER 2024

Tech 2024 Best Up-and-Coming Health Tech Company

[1]CorporateVision 2023 [2] Netty Award 2024 [3]IIA Grant

Accelerating Momentum

2021

- ✓ Listed on U.S. OTC under ticker IRME
- ✓ Raised $5.8 M

2022

- ✓ Uplisted to OTCQB
- ✓ PressureSafe™ usability study commenced in Israel with Clalit, the world's 2nd largest Health Maintenance Organization (HMO)
- ✓ Raised $3.6 M

2023

- ✓ Expanded Clalit usability study to include Rabin Medical Center
- ✓ Reported positive interim results from Clalit usability study
- ✓ Raised $1.0 M

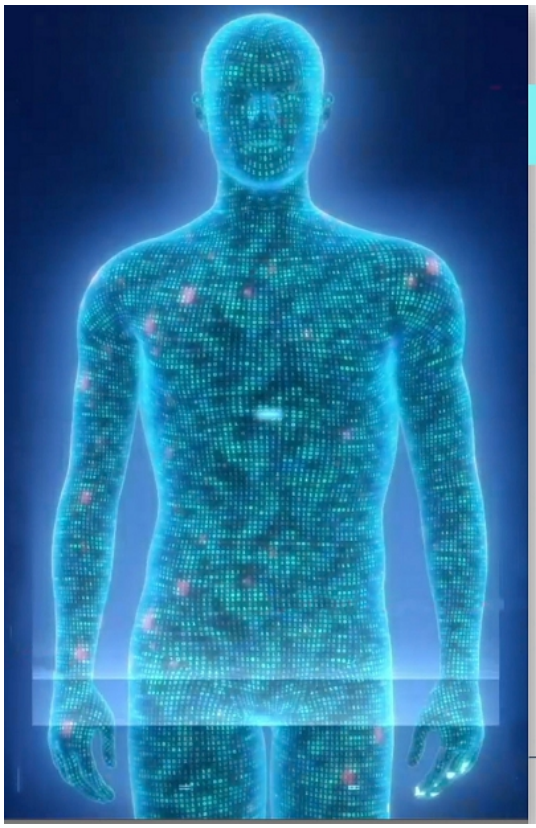
2024

- ✓ Final data from usability study with Clalit in Israel published and presented at NPIAP Conference: PressureSafe™ reduced pressure injuries by 50% during study period
- ✓ Usability study with Methodist in Texas commenced
- ✓ Raised $0.75 M
- ✓ Received $0.5 M grant from the IIA for development of DiaSafe™
- ✓ PressureSafe™ registered with the U.S. Food and Drug Administration (FDA)

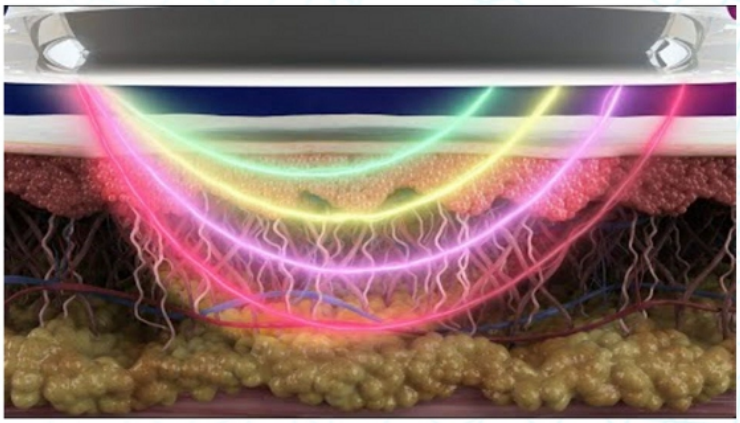
Near-Term Investment Catalysts Estimations

- Ready for marketing launch PressureSafe™ Q4 2024 in U.S.
- Sales strategy with diversified recurring revenue streams
  - ~75% gross margins
  - Clear pathway to cash flow positive at ~$10 million in revenues
- Clinical data and major milestones expected for PressureSafe™ and DiaSafe™ in 2025
- DiaSafe™ slated for U.S. launch H2 2025
- PressureSafe™ expected to launch in Europe H2 2025

Multiple shots on goal with platform technology for non-invasive, AI driven handheld device that can improve outcomes in multi-billion markets



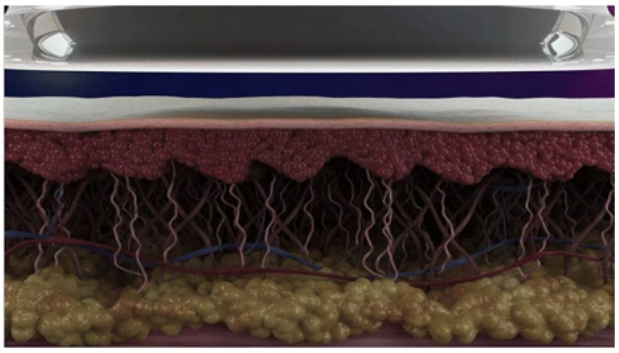
Sensing the Invisible



https://youtu.be/Zodbn3NI4XQ

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 the 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.



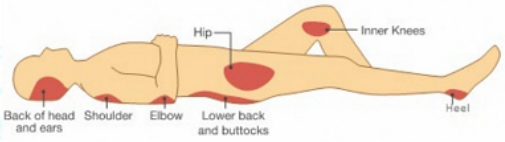
AI-Driven Point of Care Decisions

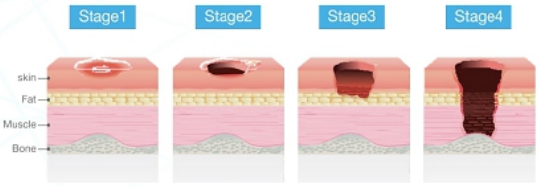
			Future Indications	
Products	 **PressureSafe™** Decision support device for detection of pressure injuries **$2.9 Billion global total addressable market[1]** **Future Tissue/Skin Indications** Monitoring open wounds, burns etc.*	 **DiaSafe™ *** Decision support device for diabetic foot ulcer detection* **$10.5 billion global diabetic foot ulcers treatment market[2]** **Future: Peripheral Artery Disease** Monitoring foot peripheral artery disease (PAD)*	 **NoBiotics*** Detection of the source of ear infections: viral vs. bacterial	 **Therapeutic Drug Monitoring*** Non-invasive measurement and monitoring of drug levels in the blood
Indications	Tissue / Skin Health	Diabetic Foot Ulcer	Ear Inflammation	Non-Invasive Drug Monitor
Platform Technology	**Real-Time | Non-Invasive | Optical Monitoring & Detection of Biomarkers & Artificial Intelligence Classification**			

*Under development , [1] Based on 8.3 million beds [2] Transparency Market Research

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.**





Sources: "A 5-Year Retrospective Study of Descriptors Associated With Identification of Stage I and Suspected Deep Tissue Pressure Ulcers in Persons with Darkly Pigmented Skin" *Wounds*, December 2014; "Current Perspectives on Pressure Injuries in Persons with Dark Skin Tones from the National Pressure Injury Advisory Panel" *Advances in Skin & Wound Care*, September 2023.

Tremendous Healthcare Burden in the U.S.

- 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
- 15% of older adults in nursing homes suffer from pressure injuries
- Nearly 40% of U.S. population is non-white; pressure injuries are harder to visually detect in people with darker skin tones

Pressure Injury Deaths Compared to Other Major Causes Annually	
Drug overdose	63,600
Pressure injuries	**60,000**
Influenza	56,000
Suicide	44,000

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.

Source: NPIAP fact sheet 2023 , "The national cost of hospital-acquired pressure injuries in the United States" International Wound Journal, January 28, 2019

Pressure Injury U.S. Market Economics

PressureSafe™ is listed with U.S. FDA*: Ready for launch Q4 2024

$1.7 billion opportunity in the U.S. upon product launch[1,2,3]

Estimated total addressable market of 75 million tests annually

CMS reimbursement code recently established - expected to accelerate market adoption

Nursing Homes: 15,300[2] nursing homes with 1.6 M beds estimated to need 102,000 devices, using 1 disposable tip per week per bed, 50 million tests annualy

Hospitals: 5,120[3] hospitals with more than 900,000[3] beds estimated to need 60,000 devices, using 2 disposable tips per week per bed 25 million tests annually

Home-Care: 11,500 home healthcare agencies serving 3 million of people[4]

* 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] Based on 2.4 million beds in the U.S. [2] U.S. Centers for Disease Control; [3] American Hospital Association; [4] American Association for Medicare Supplement Insurance

PressureSafe™

Specifically Engineered for Detection of Pressure Injuries

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.

Clinical Studies at Top Hospitals

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

PressureSafe™

Usability Study: Israel

Conducted at two hospitals owned by Clalit, the world's 2nd 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% sensitivy**
- ✓ **88% specificity**
- ✓ **No safety signals identified on 1,493 scans on 66 patients**

PressureSafe™

Usability Study: U.S.

Study initiated H1 2024 at Methodist Healthcare System of San Antonio; currently enrolling patients

A network of 85 hospitals 11,000 employees with 2,700 physicians.

Most respected provider in its region.

Study addressing challenge of early detection in people with dark skin tones.

50% of patients recruited will have dark skin.

Indication

Decision Support Device for Detection of Pressure Injuries

Regulatory Status

PressureSafe™ is listed with U.S. FDA as a Class I device that is exempt form 510(k) filing

EU, UK, and Canada: Submissions are planned

DiaSafe™

Decision support system for diabetic foot ulcer (DFU) detection, based on IR-MED's technology platform

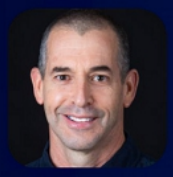
- Israel Innovation Authority examined IR-MED's platform technology and awarded a **second grant** for diabetic foot ulcers, following a prior grant for pressure injuries.
- Early detection can **reduce healthcare costs, save limbs, and save lives.**
  - More cost effective to manage in initial stages.[1]
  - Detecting and treating early DFU can significantly improve quality of life by reducing pain and mobility issues.[2]
  - Early intervention can reduce death rate associated with diabetic foot complications.[3]
- 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.[4]
- 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 Endocrinology [3] Journal of Public Health Research
[4] Transparency Markets and Research

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.



Ran Ziskind
CEO

Highly experienced high-tech innovator and company leader with two decades of expertise in launching, developing, and expanding pioneering enterprises that were later acquired by leading firms in their fields.

Ronnie Klein
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.

Anticipated Milestones**

PressureSafe™ & DiaSafe™

H2 2024

- Second stage of Methodist PressureSafe™ usability study to commence
- Proposed uplisting to national securities exchange
- PressureSafe™ ready for marketing launch in U.S.

H1 2025

- PressureSafe™ usability study expected at major northeast U.S. hospital network
- Complete IIA sponsored DiaSafe™ development milestone

H2 2025

- PressureSafe™ launch in Europe*
- DiaSafe™ launch in the U.S.

Future potential pipeline

- **NoBiotics**
- **Therapeutic Drug Monitoring**

*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.

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.

Equity Summary

Fully reporting company listed on OTCQB
Ticker: IRME

As of September 17 ,2024:

Shares Outstanding: Approximately 70 M
Held by Insiders: 39%

Attractive Business Model

- Diversified recurring revenue streams
  - By product/indication: PressureSafe™, DiaSafe™, device for peripheral artery disease
  - By customer segment: hospitals, nursing homes, home care, clinics
  - Device sales and lease
  - Disposable tip sales
  - SaaS revenues for cloud-based data
- ~75% gross profit margins
- EBITDA and cash flow positive at ~$10 million in annual revenues

IR-MED will partner with segment-specific medical device distributors that will provide sales, service, customer training, and support

Thank You

Contact:
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Sharon@ir-medical.com