

**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): **August 21, 2023**

IR-MED, INC.

Nevada
(State or Other Jurisdiction
Of incorporation)

000-56492
(commission
File Number)

84-4516398
(IRS Employer
Identification Number)

ZHR Industrial Zone Rosh Pina Israel
(Address of Principal Executive Offices)

1231400
(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.

The Company, from time to time presents and/or distributes to the investment community at various industry and other conferences slide presentations to provide updates and summaries of its business. On August 21, 2023, the Company posted an updated corporate slide presentation in the "Investors" portion of its website at <https://www.ir-medical.com>. A copy of the slide presentation is furnished pursuant to Item 7.01 as Exhibit 99.2 hereto. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.2.

Item 8.01 Other Events.

On August 21, 2023, IR-Med, Inc. (the "Company") issued a press release containing a letter from the Company's Chief Executive Officer. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated August 21, 2023
99.2	Investor presentation
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 Lefkoviz

Name: Sharon Lefkoviz

Title: Chief Financial Officer

Date: August 21, 2023



IR-MED Chairman & Interim CEO Issues Letter to Shareholders

Rosh Pina, Israel, August 21, 2023 (GLOBE NEWSWIRE) — IR-MED Inc., (“IR-MED” or the “Company”) (OTCQB:IRME), developer of a noninvasive AI-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: <https://www.ir-medical.com/wp-content/uploads/2023/08/IR-Med-Company-Presentation-7-Aug-Screen.pdf>.

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

- We plan to list PressureSafe™ 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 opportunity¹ in the U.S. and \$2.9 billion globally².
- 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

¹Based on 2.4 million beds according to the American Hospital Association and the U.S. Centers for Disease Control.

² Based on 8.3 million beds.

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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 quarter 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 of 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, 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, www.sec.gov. 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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SENSING THE INVISIBLE

NON-INVASIVE BIOMARKER ANALYSIS OF BLOOD AND TISSUE AT THE POINT OF CARE
Addressing multi billion \$ diagnostics & monitoring market

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. 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, 2022, filed with the SEC on May 11, 2023, 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 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.

CHANGING TREATMENT PARADIGMS & ECONOMICS IN MULTI-BILLION DOLLAR MARKETS¹



1) Markets and Markets 2) NPIAP Fact Sheet

Ticker: IRME | 3



PressureSafe™, IR-MED's first product, is a handheld decision support device that identifies early-stage pressure injuries **with 96% accuracy***, providing a novel solution to a \$26 B² problem and driving healthcare equality for people of all skin tones.



**Interim results from usability study conducted at two leading hospitals in Israel demonstrated 96% sensitivity based on 370 scans on 25 patients.*

Pressure Injury U.S. Market Economics

U.S. Distributor in Place and Ready for Launch H1 2024
Pending Regulatory Approval

Recurring Revenues:



Pay Per Use based on disposable tip used per patient test

Device sales/lease



SaaS for cloud-based data



\$600 M² opportunity in U.S. upon product launch

Nursing Homes:
15,600 with 1.7 million beds, typically occupied by 1.3 million patients¹

Hospitals:
~6,000 with many departments having patients at risk of developing pressure injuries, e.g. ICU, and others

Home-Care:
Millions of patients

Estimated total addressable market:
200+ million tests annually, average 2 tests/week



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

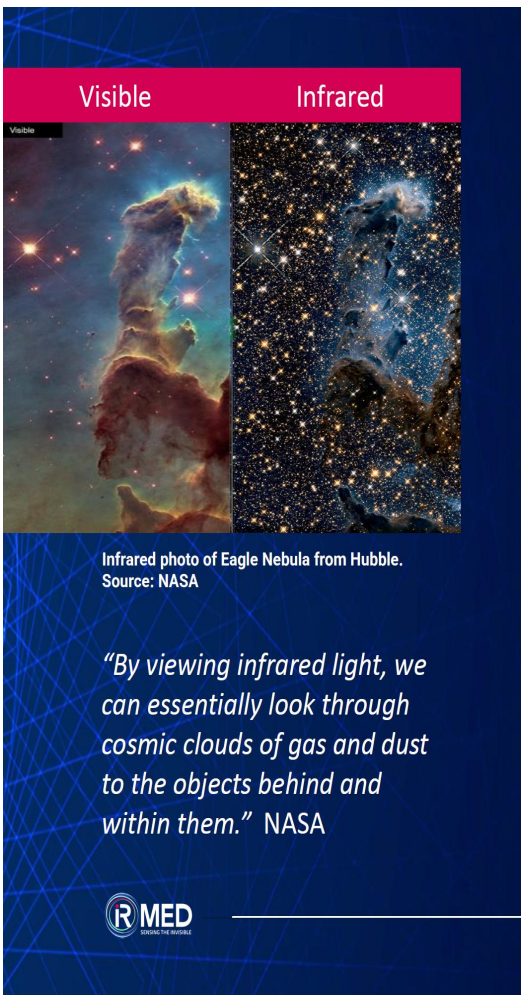
Bringing Galaxy-Seeking Technology to Point of Care: **InfraRed**

From James Webb to the human body, infrared light can be harnessed for non-invasive analysis of blood and tissue.

Infrared light was first used in a space telescope in 1983.

Today, infrared technology helps us see beyond and behind what's visible in distant galaxies.

IR-MED's patented miniature platform technology uses infrared light and proprietary Artificial Intelligence (AI) to see under the skin's surface and address substantial unmet medical needs.



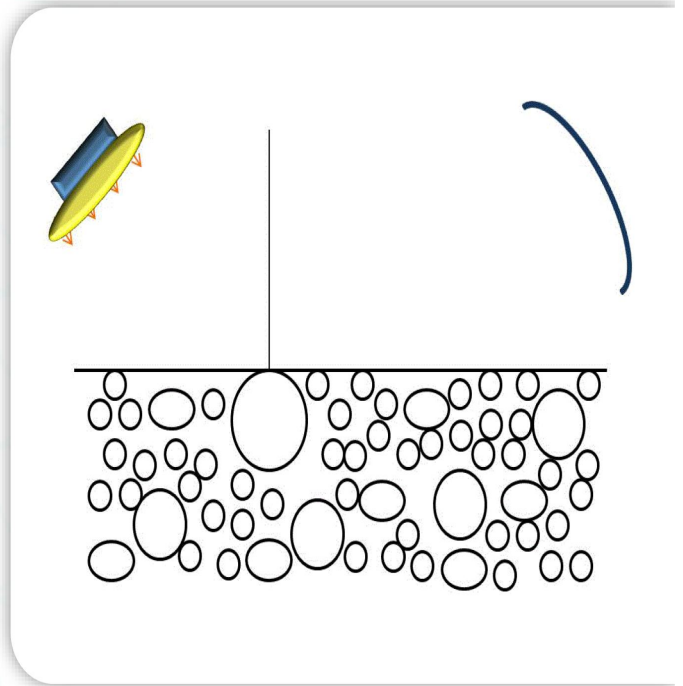
Infrared photo of Eagle Nebula from Hubble.
Source: NASA

"By viewing infrared light, we can essentially look through cosmic clouds of gas and dust to the objects behind and within them." NASA



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 an AI cloud-based 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

Products

Future Tissue/Skin Indications:

Detection of diabetic foot ulcer*
Monitoring open wounds, burns etc.*



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



Biomarker Profiling

Profiling and measurement of a large range of biomarkers to monitor disease and drug efficacy

New Indications

Indications

Tissue / Skin Health

Platform Technology

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



*Under development

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Product Pipeline



PressureSafe™ decision support device for early detection and prevention of pressure injuries

Usability Study & Advanced Development

- Target nursing homes, home care providers & hospitals
- \$26.8 B is total cost annually of pressure injuries in the U.S.
- **\$2.9 B¹ global TAM**
- Commercial launch target H1 2024*



NoBiotics for improved evaluation of ear infections: bacterial vs. viral

- Target pediatricians, family doctors, and ENT specialists
- \$11.7 B² global ear infection treatment market



Detection and Monitoring of levels of pharmaceuticals in blood

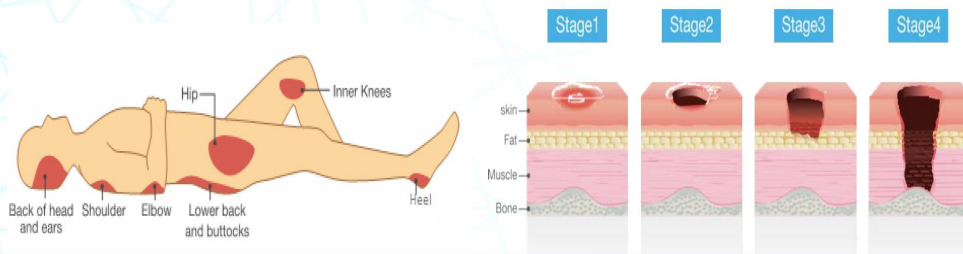
Proof of Concept Completed

- Target therapeutic drug monitoring market
- \$1.8 B³ global market
- Evaluating several drugs for GoToMarket



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



Major Source of Inequality in Healthcare

Pressure injuries are less likely to be detected with visual inspection on dark skin tones

- Delays early identification and treatment
- Results in more severe pressure injuries
- Increases financial costs for healthcare organizations

Research shows that people with dark skin tones suffer from pressure injury more than twice as much as those with lighter skin

- Higher pressure injury rates
- Higher risks of mortality from pressure injuries
- More severe pressure injuries



Source: "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.

Tremendous Healthcare Burden in the US



- 60,000 patients die every year as a direct result of pressure injuries
- 2.5 million patients per year develop a pressure injury
- Patient care cost per pressure injury ranges from \$20,900 up to \$151,700
- One of the 5 most common harms experienced by patients
- 2nd most common claim for lawsuits after wrongful death
- 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
 - 25% of patients in long term acute care
 - 12% of patients in nursing homes
 - 12% of patients in rehabilitation centers



Source: [NPIAP fact sheet 2023](#)

Features & Benefits



PressureSafe™

Fast 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 injury such as heels, sacrum etc.
- Integrates with electronic medical/hospital records
- Designed for easy expansion into a comprehensive wound management system
- Designed to improve healthcare economics through healthcare worker efficiency and reduced harm/incidence of pressure injuries



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Interim Usability Study Results



Usability Study

Conducted at 2 hospitals owned by Clalit, 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

370 scans on 25 patients

96% sensitivity

91% specificity

*No **Safety** signals were identified on 44 patients*

Indication

Decision Support Device for Detection of Pressure Injuries

Regulatory Status

U.S. FDA: Submission planned for Q4 2023

EU, UK, and Canada: Submissions are planned



Drivers for Rapid Adoption of PressureSafe™ by U.S. Hospitals, Acute & Long-Term Care Facilities

- \$26.8 billion - total cost of acute care attributable to hospital-acquired pressure injuries; Medicare beneficiaries alone account for \$22 billion
- US Centers for Medicare and Medicaid Services reduced the reimbursement related to hospital-acquired pressure injuries; Hospitals have to pay more of the financial burden of these harms
- Most hospital-acquired pressure injuries are preventable but 2.5 million people get them in acute care facilities each year
- Results in extensive harm – chronic wounds and 60,000 death annually

Pressure Injury Deaths Compared to Other Major Causes Annually

Drug overdose	63,600
Pressure injuries	60,000
Influenza	56,000
Suicide	44,000

*“Hospitals should invest more in quality improvement of early detection and care for pressure injury to avoid higher costs.”
Peer-reviewed study recommendation*



Source: “The national cost of hospital-acquired pressure injuries in the United States” *International Wound Journal*, January 28, 2019

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NoBiotics

Detects cause of ear infection: viral vs. bacterial

- 20 million¹ children annually in the U.S. visit the doctor's office due to middle ear infections
- Doctors have no way of instantly discerning whether fluid buildup behind the patient's eardrum is bacterial or viral in origin; Current tools are only accurate 50% of the time²
- Children under 6 years of age are the largest consumers of antibiotics³
- Over-usage of antibiotics raises concerns about the development of antibiotic-resistant bacteria¹
- NoBiotics is being developed as an advanced otoscope that will give doctors an immediate indication if an ear infection is viral or bacterial
- Aims to improve treatment and avoid unnecessary prescription and use of antibiotics



1) [Cochrane](#) 2) [Otolaryngologic Clinics of North America](#) 3) [Open Forum Infectious Diseases](#)



Ticker: IRME | 16

Therapeutic Drug Monitoring

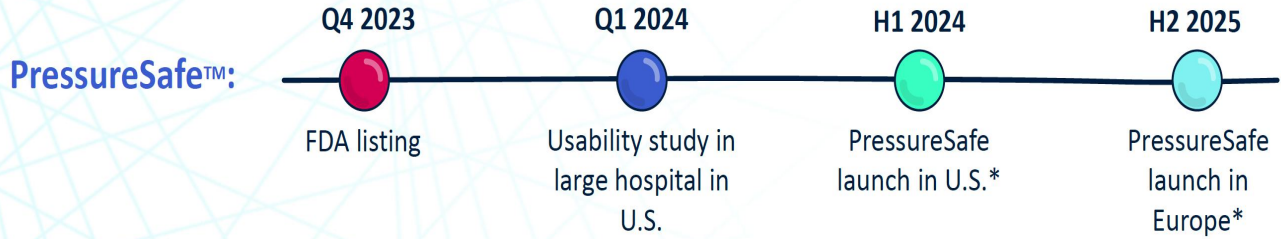


Developed as a replacement for frequent blood tests to monitor drug levels/trends in blood:

- Proof-of-concept clinical study for non-invasive spectral analysis technology monitoring real-time on-line Propofol concentration changes in 40 patients receiving IV Propofol in short anaesthesia procedures was successfully performed
- Propofol (a commonly used sedative) was used as a model drug
- Technology can be applied to large variety of drugs
- Implementation may be as a point-of-care device or as a personal wrist-based device
- **Currently evaluating drugs to select a first candidate for go-to-market**
- **Currently evaluating potential partnerships**

Upcoming Milestones

Uplist to Nasdaq/NYSE



NoBiotics: 2024: Key developments expected in biomarker profiles

Therapeutic Drug Monitoring: 2025: developments expected with regards to drug candidates and potential partnerships

Timelines are subject to change. There is inherent risk 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.

Equity Summary

Fully reporting company listed on OTCQB
Ticker: IRME

(as of July 24, 2023)

Price Per Share: \$1.12

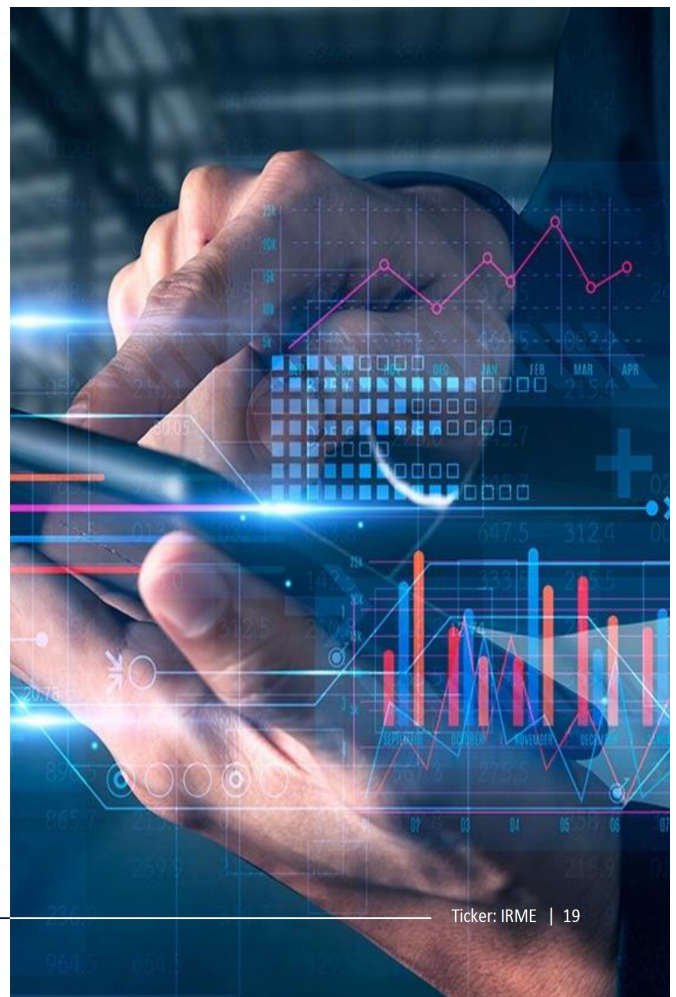
52-Week High: \$1.95

Market Cap: \$77.1 M

Shares Outstanding: 68.8 M

Held by Insiders: 64%

Cash on Hand (3/31/2023): \$2.1 M



Leadership



Oded Bashan
Executive Chairman & Interim CEO

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
Co-Founder & 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.



Yoram Drucker
VP Business Development

Successful Israeli entrepreneur and expert in the establishment of start-ups. Co-founded Pluristem (NASDAQ:PSTI), Brainstorm (NASDAQ:BCLI) and InnoCan Pharma (CSE:INNO).



Aharon Binur
Chief Development Officer

Electronics engineer with extensive experience in multidisciplinary technological management. Served as VP of R&D and Products at OTI, CTO and VP of R&D at Lehavot.



Advisory Board



Dr. Lynn Eschenbacher

PharmD, MBA, FASHP, CPEL

As an innovative executive driving positive outcomes and profitability, Dr. Eschenbacher is focused on addressing healthcare access and equity. As CEO and Founder of Echelon Health Strategies, she develops and delivers innovative strategies, operational excellence, and relationship networking to drive growth resulting in positive business outcomes and profitability. Among her many accomplishments, Dr. Eschenbacher was Chief Pharmacy Officer and VP of Medication Management at Ascension Healthcare, the second largest non-profit health system in the United States.



Dr. David Dalton

PharmD, MBA, FASHP, CPEL

Dr. Dalton is a Hall of Fame CEO, entrepreneur, pharmaceutical executive, and founder of over 40 companies. He is currently Board Director and Executive Chairman of six companies and leads the chain drug industry as the first black executive. His accolades include being an inductee in three halls of fame and a recipient of the Senatorial Medal of Freedom. Dr. Dalton was also selected by the International Forum on Advancement in Healthcare (IFAH) as one of the "Top 100 Healthcare Leaders" in 2019 and "Top 100 Healthcare Visionaries Award" in 2021.





Thank You

Contact:

Sharon Levkoviz

Chief Financial Officer

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Sharon@ir-medical.com
