



# SENSING THE INVISIBLE

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

February 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, 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 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.

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



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

Ticker: IRME | 3

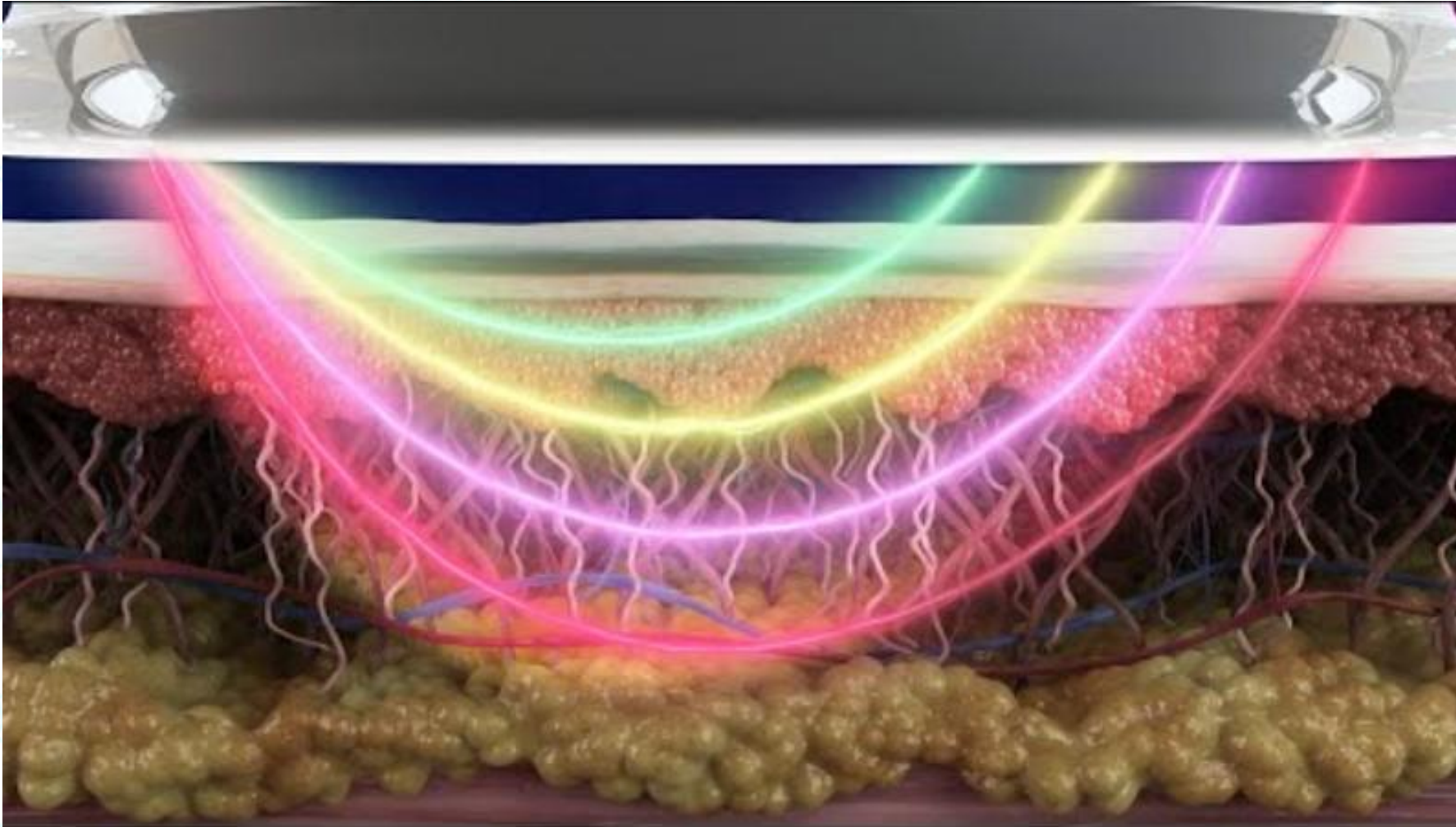


**PressureSafe™, IR-MED's first product, is a handheld device with AI-based decision support that identifies early-stage pressure injuries with 92% accuracy\*, providing a novel solution to a \$26 B<sup>2</sup> problem and driving healthcare equality for people of all skin tones.**



*\*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



# Pressure Injury U.S. Market Economics

**U.S. Distributor in Place and Ready for Launch H2 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 M<sup>2</sup> opportunity in U.S. upon product launch**

### Nursing Homes:

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

### 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

Visible

Infrared



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*



# 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.

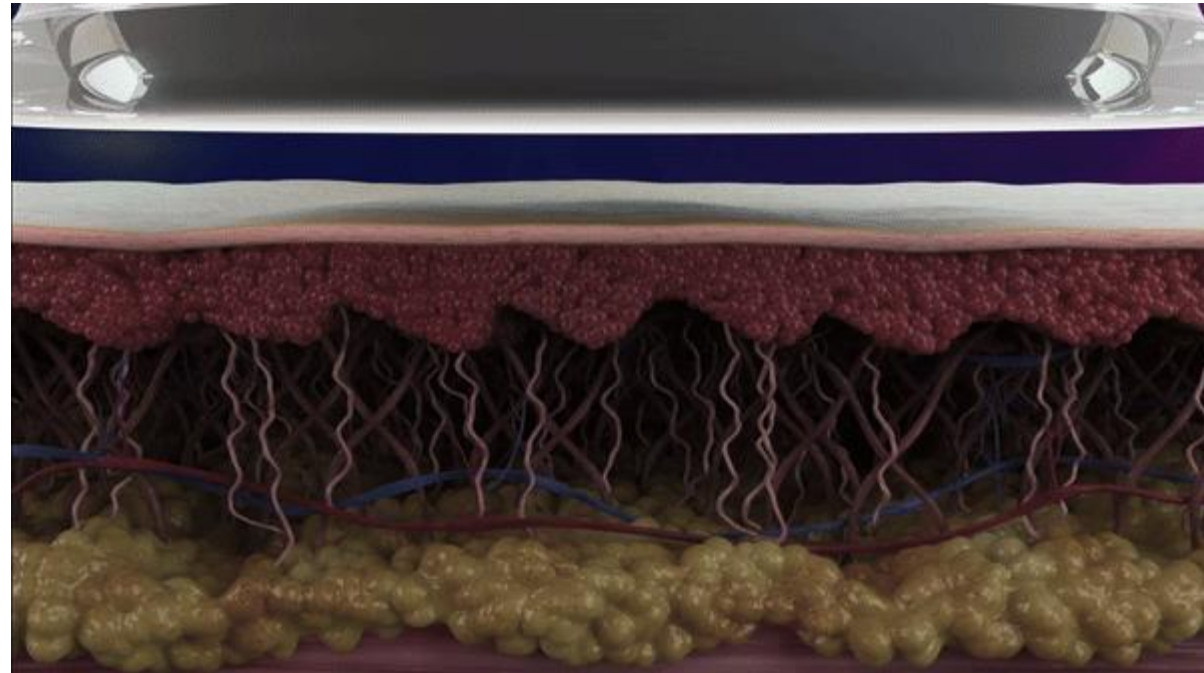
Infrared light was first used in a space telescope in 1983.

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.

# 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

### 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



## Therapeutic Drug Monitoring\*

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



## Biomarker Profiling

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

Products

Indications

Tissue / Skin Health

Ear Inflammation

Non-Invasive Drug Monitor

New Indications

Platform Technology

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



\*Under development



# 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 B<sup>1</sup> global TAM**
- Commercial launch target H2 2024\*



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

- Target pediatricians, family doctors, and ENT specialists
- \$11.7 B<sup>2</sup> global ear infection treatment market

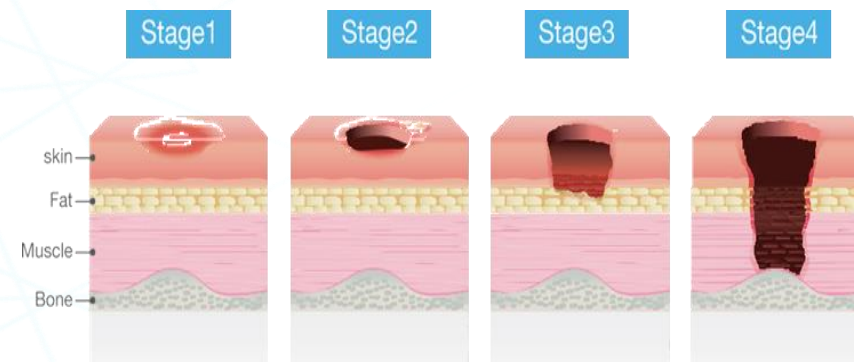
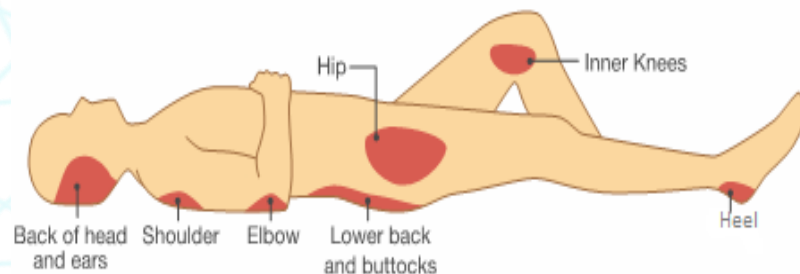


**Detection and Monitoring** of levels of pharmaceuticals in blood  
Proof of Concept Completed

- Target therapeutic drug monitoring market
- \$1.8 B<sup>3</sup> 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

**Need for improved skin assessment techniques for people with dark skin tones**

- Diversity index in the U.S. has increased to 61.1% in 2020
- Worldwide, people with dark skin tones comprise a majority of the population

**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
- Among all racial/ethnic groups in the U.S., black patients had the highest prevalence of the most severe pressure injuries while white patients had the lowest

# Tremendous Healthcare Burden in the U.S.



- 60,000 patients die every year as a direct result of pressure injuries
- \$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 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

# Features & Benefits

PressureSafe™

AI BASED

EFFECTIVE FOR ALL SKIN TONES

DISPOSABLE TIP

EMR/EHR CONNECTIVITY

CAMERA FOR DOCUMENTATION

SCANS BENEATH THE SKIN SURFACE

MULTIPLE BIOMARKERS

PERSONALIZED MEDICAL DEVICE

ERGONOMIC DESIGN  
TACTILE GRIP

REAL-TIME MEASUREMENT

HARMLESS INFRARED LIGHT

CLOUD-BASED



# 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 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



# Clinical Studies at Top Hospitals

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



## Usability Study: Israel

Conducted at 2 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

**U.S. FDA:** Submission planned for Q1 2024

**EU, UK, and Canada:** Submissions are planned

## Usability Study: U.S.

Study to launch H1 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*

# 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
- U.S. 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
<b>Pressure injuries</b>	<b>60,000</b>
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*



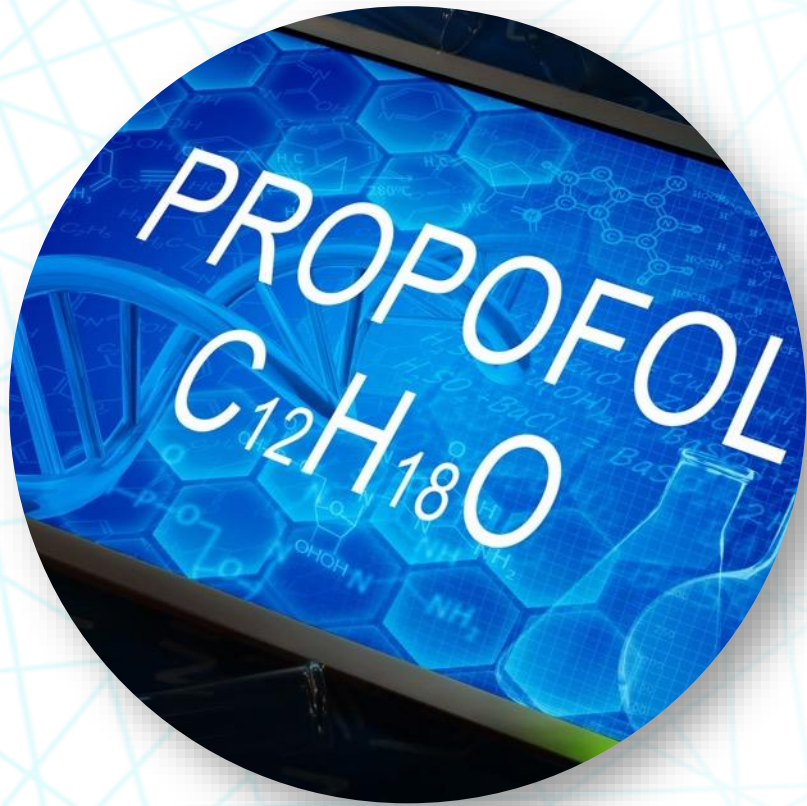
# NoBiotics

## Detects cause of ear infection: viral vs. bacterial

- 20 million<sup>1</sup> 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 time<sup>2</sup>
- Children under 6 years of age are the largest consumers of antibiotics<sup>3</sup>
- Over-usage of antibiotics raises concerns about the development of antibiotic-resistant bacteria<sup>1</sup>
- 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



# 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 February 22, 2024)

**Price Per Share: ~\$1.50**

**52-Week High: \$1.65**

**Market Cap: \$104 M**

**Shares Outstanding: 70 M**

**Held by Insiders: 64%**

**Cash on Hand (9/30/2023): \$1.5 M**



# Leadership Team



**Tzur Di-Cori**  
*CEO*

More than 30 years of experience in executive positions at several successful medical device and high-tech companies from start-up to large multinational organizations, in roles ranging from Founder to President and CEO.



**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**  
*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).

# 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.



**Richard Serbin**

*JD, RPh, LLM*

Mr. Serbin was the Chief FDA Counsel for Revlon Corporation and Johnson & Johnson Corporation. He held senior management roles at Johnson & Johnson and served on the Board of Directors of numerous Johnson & Johnson subsidiary companies including Ethicon, Ortho, Johnson & Johnson Consumer Products, Pittman-Moore, McNeil and Johnson & Johnson Development Corporation. His broader experience includes serving on the boards of numerous other companies involved in biotechnology, dermatology, veterinary medicine, female healthcare, medical devices, photodynamic therapy, surgical and consumer products.



# Thank You

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