

**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 26, 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 8.01 Other Events.

On September 26, 2023, IR-Med, Inc. (the "Company") issued a press release titled "IR-MED to Conduct Usability Study with Methodist Healthcare of San Antonio for its PressureSafe Device Which is Slated for U.S. launch in H1 2024." 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 September 26, 2023.
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:

Name: Sharon Lefkoviz

Title: Chief Financial Officer

Date: September 26, 2023



IR-MED to Conduct Usability Study with Methodist Healthcare of San Antonio for its PressureSafe Device Which is Slated for U.S. Launch in H1 2024

- *Study to address the substantial challenge of healthcare inequality in the early detection of pressure injuries in people of dark skin tones*
- *PressureSafe, a skin-color agnostic decision support device, uses AI and infrared light to see beneath skin's surface to detect biomarkers of pressure injury*
- *Interim results from a usability study in Israel indicate PressureSafe identified early-stage pressure injuries with 96% accuracy*

Rosh Pina, Israel, September 26, 2023 — IR-MED Inc., (“IR-MED” or the “Company”) (OTCQB:IRME), developer of a noninvasive artificial intelligence (AI) driven spectrographic analysis technology platform to address significant healthcare needs, announced today it has signed a Clinical Trial Agreement with the Methodist Healthcare System of San Antonio to conduct a usability study titled “Safety and Efficacy of the PressureSafe Device for Early Detection of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones.” Methodist Healthcare is recognized as the most respected healthcare provider in its region. With a network of 85 hospitals, 9 of which are acute care facilities, Methodist Healthcare employs more than 11,000 people, including 2,700 physicians.

Approximately 50% of subjects recruited for the upcoming study will have dark skin tone, thus producing comparative data on PressureSafe’s accuracy as a decision support device in detecting early-stage pressure injuries in people of darker and lighter skin tones. While early stage pressure injuries can be more difficult to see on dark skin tones, the current standard of care for the detection of pressure injuries is visual skin inspection.



Figure 1 PressureSafe, a skin color agnostic decision support device, for the early detection of pressure injuries

Research shows that people with dark skin tones suffer from pressure injury at more than twice the rate of those with lighter skin tones, as characterized by higher pressure injury rates, higher risks of mortality from pressure injuries, and more severe pressure injuries. According to a study published in September 2023 in *Advances in Skin & Wound Care*, among all racial and ethnic groups in the U.S., black patients had the highest prevalence of the most severe pressure injuries while white patients had the lowest. The peer-reviewed study goes on to state that due to increasing racial diversity in the U.S., including persons of mixed ethnic and racial backgrounds, there is an urgent need for improved techniques to identify and treat developing pressure injuries earlier.

“We are honored to partner with Methodist Healthcare, a highly prestigious hospital network for our first U.S. usability study of PressureSafe as we prepare for a potential market launch in the first half of 2024, following regulatory filings. The study has been submitted to Methodist’s Institutional Review Board for approval,” commented Dr. Yaniv Cohen, IR-MED’s Co-Founder and Chief Science Officer. “Addressing healthcare equity for the detection of pressure injuries is a priority for IR-MED. By scanning specific bio-markers beneath the skin’s surface using infrared light, we believe PressureSafe can significantly reduce pressure injury related complications regardless of skin tone. Our user-friendly handheld device can improve economics for hospitals, nursing homes, and long-term care providers, while addressing the enormous healthcare burden of this very preventable condition.”

In the U.S. alone, 60,000 patients die every year as a direct result of pressure injuries. Patient care cost per pressure injury ranges from \$20,900 up to \$151,700, for the 2.5 million patients per year who develop pressure injuries. Pressure injuries are one of the five most common harms experienced by patients and the second most common claim for lawsuits after wrongful death.

IR-MED’s prior usability study for PressureSafe was conducted at two hospitals in Israel owned by Clalit, the world’s second largest health maintenance organization (HMO). Interim results demonstrate PressureSafe detected pressure injuries with 96% sensitivity and 91% specificity. Final results are expected by the end of 2023.

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.

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 parameters and timing of the study, the expected timing of FDA approval, the potential benefits from its PressureSafe product and the expected timing of the release of its usability study conducted in Israel. Statements relating to the future performance of IR-Med are subject to many factors including, but not limited to, the sufficiency or 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 clinical/useability studies and trials, 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, and the other risks identified in our most recent annual report on Form 10-K filed on March 29, 2023 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.

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