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): **April 5, 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 8.01 Other Events.

On April 5, 2024, IR-Med, Inc. (the "Company") issued a press release titled "IR-MED's PressureSafe™ Receives FDA Listing for the Indication of Decision Support Device for Pressure Injuries." 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 April 5, 2024.
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: April 5, 2024

Exhibit 99.1

IR-MED's PressureSafe™ Receives FDA Listing for the Indication of Decision Support Device for Pressure Injuries

- ***Marks major milestone prior to launch in U.S. market***
- ***PressureSafe™ scanner and disposable pack both listed with FDA***
- ***PressureSafe™ can support early detection of pressure injuries, potentially setting a new standard of care to address a healthcare challenge that costs $26.8 billion annually in the U.S. alone***

Rosh Pina, Israel, April 5, 2024 — 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, today announced its PressureSafe™ decision support device has received U.S. Food and Drug Administration (FDA) listing or the indication of pressure injuries. PressureSafe™ is classified as a Class I device and is exempt from 510(k) premarket submission.

PressureSafe™ uses infra-red spectroscopy combined with an AI-based algorithm for the early, non-invasive, and skin color agnostic detection of pressure injuries with real-time analysis at the point of care.

"This regulatory milestone is a major step towards the commercial launch in the U.S. and signifies our commitment to advancing patient care and safety through cutting-edge medical devices," stated Ronnie Klein, IR-MED's CTO and Interim CEO. "Following our successful usability studies for PressureSafe™ in Israel, we are expanding these studies into the U.S. and expect to commence with a major hospital network in 2024."

PressureSafe achieved 92% efficacy in the early, non-invasive detection of pressure injuries, regardless of skin color, in a study conducted in Israel with the world's second largest HMO, Clalit. Nearly 1,500 scans were performed on 154 body locations.

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.

Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products.

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 FDA approval as a step towards a potential commercial launch in the U.S., the Company's intention to expand its usability studies for PressureSafe™ into the U.S., and the Company's expectations to commence with a major hospital network in 2024. 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 April 1, 2024 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.

Contact:

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