

**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): **February 8, 2023**

IR-MED INC.

Nevada
(State or Other Jurisdiction
Of incorporation)

000-56492
(commission
File Number)

83-0452269
(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.

On February 8, 2023, IR-Med, Inc. (the "Company") issued a press release reporting certain highlights of the past fiscal year and its objectives for the current year. The text of the press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of the Section, nor shall any such information or exhibits be deemed incorporated by reference in any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference to this Form 8-K in such filing.

Cautionary Statements

This filing includes "forward-looking statements." All statements other than statements of historical facts included or incorporated herein may constitute forward-looking statements. Actual results could vary significantly from those expressed or implied in such statements and are subject to a number of risks and uncertainties. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, the Company can give no assurance that such expectations will prove to be correct. The forward-looking statements involve risks and uncertainties that affect the Company's operations, financial performance, and other factors as discussed in the Company's filings with the Securities and Exchange Commission ("SEC"). Among the factors that could cause results to differ materially are those risks discussed in the periodic reports the Company files with the SEC. You are urged to carefully review and consider the cautionary statements and other disclosures made in those filings, specifically those under the heading "Risk Factors." The Company does not undertake any duty to update any forward-looking statement except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated February 8, 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: /s/ Moshe Gerber
Name: Moshe Gerber
Title: Chief Executive Officer

Date: February 8, 2023

IR-Med Gains Momentum in 2022

Biotech company makes significant progress on its PressureSafe device, teeing up entry into U.S. market in 2023

Rosh Pinna, Israel, Feb. 8, 2023 - “IR-MED” or the “Company” (OTCQB:IRME), an innovative medical device company that develops non-invasive, real-time detection devices that utilize Infrared Light Spectroscopy (IR) and Artificial Intelligence (AI) for use by healthcare professionals, today recaps a successful 2022 and forecasts consistent momentum in 2023.

During 2022, the company made substantial progress in developing non-invasive devices for various medical indications by detecting and measuring various biomarkers and molecules in human tissue and in the blood in real-time. Some notable achievements include:

Enhancing the PressureSafe Device: The company has completed its first-generation model of *PressureSafe*, a portable, handheld device that uses infrared technology (IR), spectral analysis and artificial intelligence (AI) to detect pressure injuries early. Early-stage detection of pressure wounds have the potential to reduce or prevent patient suffering, simplify medical treatment, lower healthcare costs in nursing homes, hospitals and homecare settings and improve health quality. The device also plays a key role in addressing health equity and ensuring minority groups receive equal care since pressure injuries are more difficult to detect on darker skin tones.

Preparing to Enter the U.S. Market: Pending regulatory approvals, IR-Med entered into an exclusive distribution agreement with PI Prevention Care LLC (the “Distributor”), a newly-formed entity focused on marketing to the senior care facility, hospital and homecare markets. Equipped with a team of renowned industry experts to help scale the company, the Distributor is obligated to comply with minimum purchase requirements of the device and accompanying disposables.

Adding “Nobiotics” to Its Product Pipeline: IR-Med made progress on its proof of concept for a second product, currently referred to as *Nobiotics*, which will be an advanced, handheld device that provides healthcare practitioners with real-time information about a patient’s ear infections. Doctors do not currently have an in-office, immediate tool to discern whether the cause of a patient’s infection is viral or bacterial, which could impact decision-making when deciding to use antibiotics as treatment.

Announcing an Advisory Board Member: As the company shifts toward its first sales approach, IR-Med strengthened its corporate and advisory team by announcing Dr. David Dalton to its Scientific Advisory Board. He is a hall of fame CEO, entrepreneur, pharmaceutical executive and founder of over 40 companies. In his role, Dr. Dalton will support IR-Med with analyzing the benefits of the *PressureSafe* device for Hispanic and African American populations in the United States, two groups that suffer from pressure wounds nearly twice as much as the Caucasian population due to late diagnosis.

Raising Additional Funds: In late 2022, the company completed a private placement with gross proceeds totaling \$3.6M. To date, the total investment in the company is just over \$9M.

Looking ahead to 2023, IR-Med expects to submit the *PressureSafe* device for FDA approval during the second half of the year and to move forward with the development of the *Nobiotics* device. The company is also planning to expand usability studies for the *PressureSafe* device to in both leading Israeli and U.S. hospitals.

For more information on the company or its *PressureSafe* device, please visit <https://www.ir-medical.com/>.

About IR-Med

IR-MED Inc. is developing a non-invasive 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 any invasive procedures. 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 non-invasive tissue analysis, and in the modelling and analysis of subcutaneous tissue.

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For additional information, please visit www.ir-medical.com or follow IR-Medical on [LinkedIn](#).

SAFE HARBOR/FORWARD-LOOKING STATEMENTS

Statements included in this communication, 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. 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, timing of product development, results of usability and other studies, 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. Such statements are based upon the current beliefs and expectations of management and are subject to significant risks and uncertainties and the other risks identified in our most recent annual report on Form 10-K filed on March 31, 2022 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.