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): **January 11, 2022**

IR-MED INC.

Nevada	**333-255894**	**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)	(Area 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 January 11, 2022, IR-Med, Inc. (the "Company") furnished a letter to its shareholders reporting certain highlights of the past fiscal year and its objectives for the upcoming year. The text of the letter is furnished as Exhibit 99.1 and 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"), nor shall it be deemed incorporated by reference in any of the Company's filings under the Securities Act, 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

Exhibit No.	Description
99.1	Letter to Shareholders dated January 11, 2022
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/ Rom Eliaz*
Name: Rom Eliaz
Title: Chief Executive Officer

Date: January 11, 2022

IRME Letter to Shareholders

New York, N.Y., January 11, 2022 (GLOBE NEWSWIRE) -- IR-Med, Inc. (OTCPINK: IRME).

Our non-invasive monitoring technology enters the public eye – why I'm so excited for 2022.

Dear new, old, and prospective IR-Med shareholders,

Welcome to IR-MED. After months of behind-the-scenes efforts, I'm excited to share with you what we're working–and why I'm looking forward to**2022 as a transformative period for our team and our shareholders**.

As we look back and reflect on this past year, I am proud of our team and of the progress we have made during the Covid-19 pandemic related uncertainty across all corners of the globe. While the pandemic has presented, and continues to present, many challenges that are out of our control, we remain resolute and focused on that which is within our control, including our operational, clinical and regulatory work. We continue to make progress on all fronts and firmly believe that we are on the right path towards meaningful, value-adding milestones and transformational catalysts.

IR-MED aims to become the gold standard in the detection and monitoring of medical conditions by developing and commercializing non-invasive, high usability, Real Time, Optical diagnostic devices based on the combination of Infra-Red (IR) Optical Spectrography and Artificial Intelligence (AI) technologies. Our non-invasive, user-friendly medical devices (which are currently in various stages of development) are being designed to allow for **the early detection of myriad medical conditions** Put simply, our devices are being designed to detect and monitor molecules in tissue and blood without having to take a single drop of blood from the patient and providing the physician/care giver a Decision Support System (DSS).

Our initial device incorporating our proprietary technologies targets incipient Pressure Injuries (PI) Sub-dermal before they are visible, a major challenge for care providers globally. Failure to identify and treat PIs is potentially fatal, with an estimated 60,000 mortalities in the US each year (Padula and Delarmente, Int. Wound J., 2019), and treatment is both time-consuming and costly. Currently, PI can best be treated only after appearing on the patient's skin: a sore or wound that requires considerable care. Our proprietary, user-friendly, non-invasive and real-time monitoring device – PressureSafe, is designed to provide a Decision Support System and is expected to allow for preemptive detection of PI. The device is at advanced stage of development to deal effectively with the main diagnostic problems of identifying and differentiating between Deep Tissue PI (before it becomes visible) and Stage 1 PI by providing decision support system allowing early and accurate detection. Accurate detection of PI before the Stage I phase may save lives, patient pain, stress, and substantial expense to care providers and patients alike. Our optical scanner is designed to detect Sub-dermal injuries, under the skin surface, and is equally effective regardless of skin tone, while calibrating to each patient's skin, i.e. a **personalized medical device**. PI presents a tremendous market opportunity for our company, and we believe 2022 is our budding year.

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We expect the following milestones to be achieved during 2022:

- **Proof of Concept Results H1 2022 -** In early 2022 we are planning to begin a useability study to show proof of concept with our PressureSafe device. In December 2021 we received an IRB-Helsinki Committee approval from Bet Rivka Medical Center, part of Rabin Medical Center in Israel. We expect results quickly and are highly optimistic about outcomes given clinician experience with this device to date.
- **File For FDA Clearance - H1 2022 -** We plan to file for 510(k) clearance with the United States FDA in the first half of 2022.
- **Production capabilities - Q4 2022** – By the end of the year, subject to FDA clearance, we are planning to start production activities in order to be ready to launch into the lucrative US PI market.
- **JV and BD Efforts 2022 -** We have begun business development efforts to identify nursing homes, home care organizations, and JV or licensing opportunities with both potential customers and partners.
- **Corporate and Financial Development** – We concurrently initiated a strategy to upgrade our position in the public markets and increase IR-Med visibility to a wider range of investors and have submitted application materials to OTC Markets Group to up list to the OTCQB market tier. The OTCQB Venture Market is designed for developing and entrepreneurial companies. Companies must be current in their financial reporting and undergo an annual verification and management certification process, including meeting a minimum bid price and other financial conditions. With more compliance and quality standards, the OTCQB provides investors improved visibility to enhance trading decisions. The listing of IR-Med's common stock on the OTCQB remains subject to the approval of the OTCQB and the satisfaction of applicable listing requirements. IR-Med already meets one of OTCQB Venture Market compliance requirements by having audited annual financials prepared in accordance with U.S. GAAP by a PCAOB auditor and maintains a Verified Company Profile at OTCMarkets.com.

In addition to the *PressureSafe* device, we are concurrently developing an advanced otoscope called Nobiotics to provide physicians with immediate information as to whether an ear infection is viral or bacterial in nature. Over 20 million children in the U.S. and E.U. are affected by ear infections each year (Suaya et al., Vaccine, 2018) and diagnosing a causal pathogen behind the eardrum is nearly impossible. Our device will work through IR-spectrographic analysis, like PressureSafe, to decision support system for ideal treatment for young children.

Reflecting on the considerable work that's gone into our technology to date, I'm thrilled that we're now public facing. We thank you for your continued support and interest.
Looking forward,

Dr. Rom Eliaz, Chief Executive Officer

About IR-Med

IR-Med Inc., is developing non-invasive spectrographic analysis technology, allowing healthcare professions to detect and measure different molecules in the blood and in human tissue in real-time 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 and which calibrated personally to each patient's skin, primarily caused by prolonged pressure associated with bed confinement. IR-med skin-device-interphase development of personalized medical devices allows high accuracy readings from the human body in a non-invasive method, that may provide caregiver the optimal decision support-system in cases where uncertainties disturb physicians in their decision processes.

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Currently, IR-med holds patents protecting its innovation in the noninvasive tissue analysis, and in the modeling and analysis of subcutaneous tissue. The company is in preliminary process of examining the filing of additional patents applications.

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. 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, 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, successful up-list to OTCQB, and the other risks identified in the S-1 resale registration statement filed 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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