UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

MARK ONE

☒ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period ended September 30, 2023

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the transition period from ________ to ________

Commission File Number: **000-56492**

IR-Med, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**84-4516398**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
N/A	N/A	N/A

Securities registered pursuant to Section 12(g) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	IRME	OTCQB

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 14, 2023, there were outstanding 69,924,240 shares of the registrant's common stock, par value $0.001 per share.

IR-MED, INC.
Form 10-Q
September 30, 2023

Interim Unaudited Condensed Consolidated Balance Sheets

	September 30 2023	December 31 2022
	U.S dollars (in thousands)	
Assets		
Current assets		
Cash and cash equivalents	**1,524**	3,002
Accounts receivable	**83**	55
Total current assets	**1,607**	3,057
Non- current assets		
Long term restricted deposit	**11**	11
Operating lease right of use assets	**100**	155
Property and equipment, net	**55**	71
Total non-current assets	**166**	237
Total assets	**1,773**	3,294
Liabilities and stockholders' equity		
Current liabilities		
Trade and other payables	**407**	500
Stockholders' loans	**152**	162
Total current liabilities	**559**	662
Non-current liabilities		
Long term lease liability	**2**	40
Total non-current liabilities	**2**	40
Total liabilities	**561**	702
Stockholders' Equity		
Common stock, par value $0.001 per share, 250,000,000, shares authorized. 69,873,424 and 68,808,970 shares issued as of September 30, 2023, and December 31, 2022, respectively.	**69**	68
Additional paid-in capital	**14,711**	12,454
Accumulated deficit	**(13,568)**	(9,930)
Total stockholders' equity	**1,212**	2,592
Total liabilities and stockholders' equity	**1,773**	3,294

The accompanying notes are an integral part of these interim unaudited condensed financial statements.

Interim Unaudited Condensed Consolidated Statements of Operations

	For the three-month period ended September 30		For the nine-month period ended September 30	
	2023	**2022**	**2023**	**2022**
	U.S dollars (in thousands)			
Research and development expenses	**469**	468	**1,570**	1,357
Marketing expenses	**297**	24	**631**	205
General and administrative expenses	**431**	384	**1,448**	1,138
Total operating loss	**1,197**	876	**3,649**	2,700
Financial income, net	**(18)**	(20)	**(11)**	(56)
Loss for the period	**1,179**	856	**3,638**	2,644
Basic and dilutive loss per common stock (in dollars)	**(0.02)**	(0.01)	**(0.05)**	(0.04)
Weighted average number of ordinary shares	**68,836,598**	68,720,970	**69,233,573**	67,186,877

The accompanying notes are an integral part of these interim unaudited condensed financial statements.

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the nine-month period ended September 30, 2023					
Balance as of January 1, 2023	**68,808,970**	**68**	**12,454**	**(9,930)**	**2,592**
Private placement of common stock and warrants.	**1,000,000**	**1**	**999**	**-**	**1,000**
Stock-based compensation	**64,454**		**1,258**		**1,258**
Loss for the period	-	-	-	**(3,638)**	**(3,638)**
Balance as of September 30, 2023	**69,873,424**	**69**	**14,711**	**(13,568)**	**1,212**

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the nine-month period ended September 30, 2022					
Balance as of January 1, 2022	64,601,649	64	7,503	(5,196)	2,371
Private placement of common stock and warrants, net	4,119,321	4	3,621	-	3,625
Stock-based compensation	-	-	226	-	226
Loss for the period	-	-	-	(2,644)	(2,644)
Balance as of September 30, 2022	68,720,970	68	11,350	(7,840)	3,578

The accompanying notes are an integral part of these interim unaudited condensed financial statements.

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the three-month period ended September 30, 2023					
Balance as of July 1, 2023	**69,829,424**	**69**	**14,328**	**(12,389)**	**2,008**
Stock-based compensation	**44,000**	-	**383**	-	**383**
Loss for the period	-	-	-	**(1,179)**	**(1,179)**
Balance as of September 30, 2023	**69,873,424**	**69**	**14,711**	**(13,568)**	**1,212**

(*) Represents an amount less than US$ 1 thousand

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the three-month period ended September 30, 2022					
Balance as of July 1, 2022	68,238,013	68	10,801	(6,984)	3,885
Private placement of common stock and warrants, net	482,957	*	425		425
Stock-based compensation	-	-	124	-	124
Loss for the period	-	-	-	(856)	(856)
Balance as of September 30, 2022	68,720,970	68	11,350	(7,840)	3,578

(*)Represents an amount less than US$ 1 thousand

The accompanying notes are an integral part of these interim unaudited condensed financial statements.

Interim Unaudited Condensed Consolidated Statements of Cash Flows

	For the nine-month period ended	
	September 30 2023	September 30 2022
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	**(3,638)**	(2,644)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	**1,258**	226
Depreciation	**17**	10
Accrued financial income	**(11)**	(18)
Increase in accounts receivable	**(28)**	(16)
Decrease in trade and other payables	**(76)**	(154)
Net cash used in operating activities	**(2,478)**	(2,596)
Cash flows from investing activities		
Purchase of property and equipment	**(1)**	(48)
Investment in restricted deposit	**-**	(9)
Net cash used in investing activities	**(1)**	(57)
Cash flows from financing activities		
Proceeds from private placement of common stock and warrants, net (see also note 1.B)	**1,000**	3,625
Net cash provided by financing activities	**1,000**	3,625
Effect of exchange rate changes on cash and cash equivalents	**1**	(1)
Net (decrease) increase in cash and cash equivalents	**(1,478)**	971
Cash and cash equivalents as at the beginning of the period	**3,002**	2,815
Cash and cash equivalents as at the end of the period	**1,524**	3,786

The accompanying notes are an integral part of these interim unaudited condensed financial statements.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 1 – General

A. Description of Business

IR-Med, Inc. (OTC QB: IRME, hereinafter: the "Company") was incorporated in Nevada in 2007 and is a holding company. It also operates through IR. Med Ltd., the Company's wholly owned subsidiary (the "Subsidiary").

The registered office of IR-Med, Inc. and the corporate headquarters and research facility of the Subsidiary are located in Rosh Pina, Israel.

The Company is a development stage medical device. company developing its technology through its Subsidiary and is utilizing Infra-Red light spectroscopy (IR), combined with an Artificial Intelligence (AI) technology platform, to develop non-invasive devices for various medical indications, by detecting and measuring various biomarkers and molecules in the blood and in human tissue in real-time. The initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate information for detection, which is expected to reduce healthcare expenses, reduce widespread reliance on antibiotics administration, and other interventional options, and optimize the delivery of targeted medical services and, as a result, improve the efficacy and safety of administered treatments.

B. Going Concern

These consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP") assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. However, substantial doubt about the Company's ability to continue as a going concern exists.

The Company is in its development stage and does not expect to generate significant revenue until such time as the Company shall have completed the design and development of its initial product candidate and obtained the requisite approvals to market its products. During the nine months ended September 30, 2023, the Company has incurred losses of $ 3,638 thousand and had a negative cash flow from operating activities of $2,478 thousand. The accumulated deficit as of September 30, 2023, is $13,568 thousand.

Management's plans regarding these matters include continued development and marketing of the Company's products, as well as seeking additional financing arrangements. Although management continues to pursue these plans, there is no assurance that the Company will be successful in raising the needed capital from revenues or financing on commercially acceptable terms. See also note 6 to these financial statements regarding the Iron Swords War (as defined herein) which has caused additional difficulties in management's efforts to seek additional financing arrangements.

On June 12, 2023, the Company entered into a subscription agreement with one investor pursuant to which the Company issued 1,000,000 shares of its common stock at a per share price of $1.00, and warrants to purchase up to an additional 1,000,000 shares of common stock at a per share exercise price of $1.40. The warrants expire on the third anniversary from the date of issuance of the warrant to the holder. The Company is entitled to accelerate the warrant exercise period for all or a part of the then outstanding warrants by written notice to the holders if the publicly traded price of the Company's common stock equals or exceeds $2.50 per share (which amount may be adjusted for certain capital events, such as stock splits, as described herein) and the corresponding average daily trading volume during such period shall equal or exceed 75,000 shares, in each case for the preceding forty (40) consecutive trading days. The Company received aggregate proceeds of $1,000,000 from this financing.

As a result of the Company's financial condition, substantial doubt exists that the Company will be able to continue as a going concern for one year from the issuance date of these financial statements.

The consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were unable to continue as a going concern.

Note 2 - Interim Unaudited Financial Information

The accompanying interim unaudited financial statements of the Company (the "Interim Financial Statements") have been prepared in accordance with U.S. GAAP for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements and therefore should be read in conjunction with the Company's Annual Report on Form 10-K/A for the year ended December 31, 2022 (the "2022 Annual Report"), filed with the Securities and Exchange Commission (the "SEC").

In the opinion of management, all adjustments considered necessary for a fair statement, consisting of normal recurring adjustments, have been included. Operating results for the three and nine months period ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023.

Use of Estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the Interim Financial Statements, and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions include fair value of warrants and the share-based compensation. Actual results could differ from those estimates.

Note 3 – Significant Accounting Policies

These interim unaudited condensed consolidated financial statements have been prepared according to the same accounting policies as those discussed in the Company's 2022 Annual Report.

Note 4 – Stock options plan

On December 23, 2020, the Company's board of directors approved, and the shareholders adopted, a share-based compensation plan (the "2020 Incentive Stock Plan") for future grants by the Company to officers, directors, employees and consultants.

As of September 30, 2023, the Company awarded to its employees and service providers options to purchase up to 15,744,175 shares of common stock, of which options for 7,821,175 shares were at an exercise price of $0.32 per share, options for 7,243,000 shares were at an exercise price of $ 0.58 per share, options for 480,000 shares were at an exercise price of $0.01 per share and options for 200,000 shares were at an exercise price of $0.64 per share.

As of September 30, 2023, options for 11,601,688 shares were vested and the remaining balance has a vesting period ranging between one to four years. The options are exercisable for periods ranging between three to ten years from the vesting date.

The aforementioned grants were approved following the adoption of the 2020 Incentive Stock Plan and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021. The Company recorded in the statement of operations a non-cash expense of $1,258 thousand and $226 thousand during the nine months ended September 30, 2023 and 2022, respectively.

The stock-based compensation expenses for the three and nine months ended September 30, 2023 and 2022 were recognized in the statements of operations as follows:

	For the three-month period ended September 30		**For the nine-month period ended September 30**	
	2023	**2022**	**2023**	**2022**
	U.S dollars (in thousands)			
Research and development expenses	**36**	18	**119**	65
Marketing expenses	**173**	-	**486**	-
General and administrative expenses	**174**	106	**653**	161
	383	124	**1,258**	226

Note 4 - Stock options plan (cont'd)

The following table sets forth information about the weighted-average fair value of options granted to employees and service providers during the nine month periods ended September 30, 2023 and 2022, using the Black- Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

	For the nine-month period ended	
	September 30, 2023	September 30, 2022
Dividend yields (see (I) below)	0.0%	0.0%
Share price (in U.S. dollar) (see (II) below)	0.53-0.64	0.26-0.53
Expected volatility (see (III) below)	116% - 95.37%	82.77% - 142.57%
Risk-free interest rates (see (IV) below)	3.61% - 4.16%	0.17% - 2.63%
Expected life (in years) (see (V) below)	5 - 14.79	1.5 - 14.79

I. The Company used 0% as its expected dividend yield, based on historic policies and future plans.

II The Company's common stocks are quoted on the OTCQB. However, the Company considers its share price as it is traded on OTCQB to not be an appropriate representation of fair value, since it is not traded on an active market. The Company determined that the market is inactive due to low level of activity of the Company's common stock, stale or non-current price quotes and price quotes that vary substantially either over time or among market makers. Consequently, the price of the Company's common stock has been determined based on private placement equity offerings conducted in April 2021 , July 2022 and June 2023 consisting of units comprised of shares of common stock and warrants, at a per unit purchase price of $0.64, $0.88 and $1 respectively. In order to evaluate the price per share, the warrant value has been deducted from the total unit price.

III As the Company is at its early stage of operation, there is not sufficient historical volatility for the expected term of the stock options. Therefore, the Company uses an average historical share price volatility based on an analysis of reported data for a peer group of comparable publicly traded companies which were selected based upon industry similarities.

IV. The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of the grant.

V. The expected life of the granted options was determined based on the estimated behavior of the grantees; since most of the grantees are executives, the Company assumed that the large majority of the options will be exercised prior to their expiration.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 5 - Commitments and contingencies

On May 29, 2023, a lawsuit was filed against the Company, the Subsidiary and Mr. Aharon Klein, a Company Director and the Company's Chief Technology Officer in the Tel Aviv District Court of Israel, by an individual who provided, on s part time basis, certain consulting services to the Subsidiary between October 2015 through October 2016, prior to the acquisition of the Subsidiary by the Company. The suit alleges breach of contract by the defendants based on non-payment of amounts purportedly owed to the plaintiff in respect of the services rendered, including the market value of the Company's common stock that the plaintiff alleges should have been issued to him in respect of services. The suit seeks declaratory judgment that the defendants breached certain agreements with the plaintiff and claimed damages in the aggregate amount of approximately $2.1 million based on the current exchange rate between the U.S. Dollar and the Israeli NIS.

The Company records a provision in its financial statements to the extent that it concludes that a contingent liability is probable, and the amount thereof is reasonably estimable. Based upon the status of the case described above, management's assessments of the likelihood of damages, and the advice of counsel, no provisions have been made regarding the matter disclosed in this note. Litigation outcomes and contingencies are unpredictable, and excessive verdicts can occur. Accordingly, management's assessments involve complex judgments about future events and often rely heavily on estimates and assumptions.

Note 6 - Subsequent events

Following the brutal attacks on Israel, the mobilization of army reserves and the Israeli Government declaring a state of war (the "Iron Swords War") in October 2023, there has been a decrease in Israel's economic and business activity. The security situation has led, inter alia, to a disruption in the chain of supply and production, a decrease in the volume of national transportation, a shortage in manpower as well as a decrease in the value of financial assets and a rise in the exchange rate of foreign currencies in relation to the shekel.

At this time, the Company has assessed, on the basis of the information it has as at the date of approval of these financial statements, that the current events and the escalation in security in Israel, may have a material effect on the business plans of the Company in the short term. As a result of the movement and work restrictions in Israel, the Company has begun operating on a limited scale, and most of the Company's employees have been instructed to work from home. These restrictions and the shortage in manpower may cause delays in the Company's research and development activities and in its marketing efforts. In addition, the situation has brought further difficulties in management's efforts to seek additional financing arrangements. Since this is an event that is not under the control of the Company, and matters such as the fighting continuing or stopping may affect the Company's assessments, as at the reporting date the Company is unable to assess the extent of the effect of the Iron Swords War on its business activities and on the business activities of its subsidiaries, and on their medium and long term results. The Company is continuing to regularly follow developments on the matter and will continue to examine the effects on its operations and the value of its assets.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws, and is subject to the safe-harbor created by such Act and laws. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms, or other variations thereon or comparable terminology. The statements herein and their implications are merely predictions and therefore inherently subject to known and unknown risks, uncertainties, assumptions and other factors that may cause actual results, performance levels of activity, or our achievements, or industry results to be materially different from those contemplated by the forward-looking statements. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading "Risk Factors" in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission, or the SEC, on March 29, 2023. As used in this quarterly report, the terms "we", "us", "our", the "Company" and "IR-Med" mean IR-Med, Inc. and our wholly-owned subsidiary IR. Med Ltd. unless otherwise indicated or as otherwise required by the context.

Overview

We are a development stage medical device company that is developing non-invasive devices for various medical indications, by detecting and measuring various biomarkers and molecules in the blood and in human tissue in real-time, allowing healthcare professionals to detect and measure different molecules in the blood and in human tissue in real-time without any invasive procedures. Our initial product candidates are currently in various stages of development.

Our initial product under development, *PressureSafe*, is a handheld optical monitoring device that is being developed to support early detection of pressure injuries to the skin and underlying tissue, regardless of skin tone. The device, which is calibrated personally to each patient's skin, has a disposable tip, and detects pressure injuries, which are primarily caused by prolonged pressure associated with bed confinement. Our skin-device-interphase development of personalized medical devices allows high accuracy readings from the human body in a non-invasive method, which may provide caregivers the optimal decision support-system (DSS) that is needed in cases where uncertainties disturb physicians in their decision processes. We plan to launch *PressureSafe* as a decision support system (DSS) tool for care givers in hospitals, nursing homes and home-care companies.

We are also in the preliminary stage of research and development of an innovative otoscope, *Nobiotics*, to support physicians with an immediate indication as to whether mid-ear infection (Otitis Media), a common malady in children, is of a bacterial origin and thus requiring antibiotic treatment, or of a viral origin and consequently does not require antibiotic treatment.

Our technology platform utilizes Artificial Intelligence (AI). AI is a broad term generally used to describe conditions where a machine mimics "cognitive" functions associated with human intelligence, such as "learning" and "problem solving. Basic AI includes machine learning, where a machine uses algorithms to parse data, learn from it, and then suggest a determination or prediction about a given phenomenon. The machine is "trained" using large amounts of data and algorithms that provide it with the ability to learn how to perform various tasks.

The global diagnostics market is driven in large by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis remains a common occurrence.

Our initial focus is on the development of decision support system (DSS) solutions utilizing our proprietary platform for the pre-emptive diagnosis of pressure injuries and of mid-ear infections detection. Our current business plan focuses on two principal medical devices currently in development:

1. *PressureSafe* — a handheld optical monitoring device that is being developed to support early detection of pressure injuries to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement; and

2. *Nobiotics,* an innovative otoscope, being designed to support physicians with an immediate indication as to whether mid-ear infection (Otitis Media), a common malady in children, is of a bacterial origin and thus requiring antibiotic treatment, or of a viral origin and does not require antibiotic treatment.

Our product candidates are in various stages of development. The *PressureSafe* device is in an advanced stage of development and is planned to be our first go-to-market product, and the *NoBiotics* is in initial stage of research and development.

We have completed the development of the first generation *PressureSafe* prototype in the second quarter of 2022. In June 2022, IR Med. Ltd., our wholly owned subsidiary, entered into a study agreement with Beit Rivka, a Large Geriatric Hospital in Israel associated with Clalit, the largest Health Maintenance Organization (HMO) in Israel, to conduct a usability study of *Pressuresafe*.

On July 17, 2023, we published our interim report of usability study performed in Israel in leading medical centers with the following results. In that study, *PressureSafe* demonstrated very high efficacy in noninvasively detecting the presence and absence of pressure injuries below the skin's surface. *PressureSafe* accurately detected the presence of a pressure injury in 96% of cases. In addition, *PressureSafe* correctly determined no wound was present in 91% of cases. The study was conducted at two medical centers owned by Clalit, the world's second largest health maintenance organization (HMO) and the largest in Israel, Beit Rivka Hospital and Rabin Medical Center both in Petah Tikva, where 370 *PressureSafe* scans were performed on 25 patients who had Stage 1 pressure injuries or deep tissue injuries. No device related safety issues were reported in the total of 44 patients evaluated for safety.

On September 26, 2023, we announced that we signed a Clinical Trial Agreement with the Methodist Healthcare System of San Antonio to conduct a useability 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.

We are currently working on completing the development of the commercial version of the *PressureSafe* device, planned to be launched during 2024, following registration and listing under the U.S. Food and Drug Administration ("FDA").

New Chief Executive Officer

Effective as of October 15, 2023, the Board appointed Mr. Tzur Di-Cori to serve as our Chief Executive Officer (CEO). Mr. Di-Cori will also serve as the Chief Executive Officer of our wholly-owned subsidiary, IR-Med LTD., an Israeli corporation.

Key Financial Terms and Metrics

The following discussion summarizes the key factors our management believes are necessary for an understanding of our consolidated financial statements.

Revenues

We have not generated any revenues from product sales to date.

Research and Development Expenses

The process of researching and developing our product candidates is lengthy, unpredictable, and subject to many risks. We expect to continue incurring substantial expenses for the next several years as we continue to develop our product candidates. We are unable, with any certainty, to estimate either the costs or the timelines in which those expenses will be incurred. Our current development plans focus on the development of our *PressureSafe* and *Nobiotics* diagnostic devices. The design and development of these devices will consume a large proportion of our current, as well as projected, resources.

Our research and development costs are comprised of:

● internal recurring costs, such as personnel-related costs (salaries, employee benefits, equity compensation and other costs), materials and supplies, facilities and maintenance costs attributable to research and development functions; and

● fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing, related testing, and clinical trial activities.

Marketing

Marketing expenses consist primarily of salaries, employee benefits, equity compensation, and other personnel-related costs associated with executive and other support staff. Other significant marketing expenses include the costs associated with professional fees to develop our marketing strategy.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, employee benefits, equity compensation, and other personnel-related costs associated with executive, administrative and other support staff. Other significant general and administrative expenses include the costs associated with professional fees for accounting, auditing, insurance costs, consulting and legal services, along with facility and maintenance costs attributable to general and administrative functions.

Financial Expenses

Financial expenses consist primarily impact of exchange rate derived from re-measurement of monetary balance sheet items denominated in non-dollar currencies. Other financial expenses include bank's fees and interest on stockholders' loans.

Results of Operations

Comparison of the nine months ended September 30, 2023 to the nine months ended September 30, 2022

Revenues. During the nine-month period ended September 30, 2023 and 2022, we did not record any revenues from operation.

Research and Development Expenses. Research and development expenses consist of salaries and related expenses, consulting fees, service provider costs, and overhead expenses. Research and development expenses increased from $1,357,000 during the nine months ended September 30, 2022, to $1,570,000 during the corresponding nine month period in 2023. The increase resulted primarily from increased use of third-party contractors for further research and development activities, the performance of usability studies for our PressureSafe device and non-cash expenses recorded relating to stock-based compensation to employees.

Marketing Expenses. Marketing expenses consist primarily of salaries and professional services. Marketing expenses increased from $205,000 during the nine months ended September 30, 2022 to $631,000 during the corresponding nine month period in 2023. The increase in marketing expenses resulted primarily from non-cash expenses attributable to stock-based compensation to service providers. This increase was partially offset by a reduction in payroll expenses.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and related expenses and other non-personnel related expenses, such as legal and accounting related expenses. General and administrative expenses increased from $1,138,000 during the nine months ended September 30, 2022 to $1,448,000 in the corresponding nine months period in 2023. The increase in general and administrative expenses resulted primarily from non-cash expenses attributable to stock-based compensation to our directors, officers, and service providers. This increase was partially offset by a reduction in professional services.

Loss. Loss for the nine months ended September 30, 2022 was $2,644,000 compared to $3,638,000 for the corresponding nine month period in 2023. The increase in net loss is primarily attributable to the increase in non-cash expenses due to stock-based compensation to directors, officers and service providers, utilization of third party contractors for further research and development activities and the conduct of usability studies for our *PressureSafe* device. These increases were partially offset by the reduction in professional services in general and administrative activities and by the reduction of payroll expenses related to marketing.

	For the nine month ended September 30,	
	2023	**2022**
	U.S. dollars (in thousands)	
Research and development expenses	**1,570**	1,357
Marketing expenses	**631**	205
General and administrative expenses	**1,448**	1,138
Total operating expenses	**3,649**	2,700
Financial income, net	**(11)**	(56)
Loss for the period	**3,638**	2,644

Comparison of the three months ended September 30, 2023 to the three months ended September 30, 2022

Revenues. During the three-month period ended September 30, 2023 and 2022, we did not record any revenues from operation.

Research and Development Expenses. Research and development expenses consist of salaries and related expenses, consulting fees, service provider costs, and overhead expenses. Research and development expenses increased from $468,000 during the three months ended September 30, 2022 to $469,000 during the corresponding three month period in 2023. The increase resulted primarily from the increase of non-cash expenses recorded relating to stock-based compensation to employees. The increase was partially offset by the reduction in usability studies activities for our PressureSafe device due to the completion of our usability study in Israel.

Marketing Expenses. Marketing expenses consist primarily of salaries and professional services. Marketing expenses increased from $24,000 during the three months ended September 30, 2022 to $297,000 during the corresponding three month period in 2023. The increase in marketing expenses resulted primarily from non-cash expenses attributable to stock-based compensation to service providers and use of third-party consultants. This increase was partially offset by a reduction in payroll expenses.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and related expenses and other non-personnel related expenses, such as legal and accounting related expenses. General and administrative expenses increased from $384,000 during the three months ended September 30, 2022 to $431,000 in the corresponding three month period in 2023. The increase in general and administrative expenses resulted primarily from non-cash expenses attributable to stock-based compensation to our directors, officers, and service providers. This increase was partially offset by a reduction in professional services.

Loss. Loss for the three months ended September 30, 2022 was $856,000 compared to $1,179,000 for the corresponding three month period in 2023. The increase in net loss is primarily attributable to non-cash expenses due to stock-based compensation to directors, officers, and service providers, use of third-party consultants related to marketing activity. This increase was partially offset by the reduction in usability studies activities for our PressureSafe device due to the completion of our usability study in Israel and the reduction of payroll expenses related to marketing.

	For the three month ended September 30,	
	2023	2022
	U.S. dollars (in thousands)	
Research and development expenses	**469**	468
Marketing expenses	**297**	24
General and administrative expenses	**431**	384
Total operating expenses	**1,197**	876
Financial income, net	**(18)**	(20)
Loss for the period	**1,179**	856

Financial Condition, Liquidity and Capital Resources

We are subject to risks common to companies in the medical device industry, including but not limited to, the need for additional capital, the need to obtain marketing approval and reimbursement for any product candidate that we may identify and develop, the need to successfully commercialize and gain market acceptance of our product candidates, dependence on key personnel, protection of proprietary technology, compliance with government regulations, development of technological innovations by competitors, reliance on third-party manufacturers and the ability to transition from pilot-scale production to large-scale manufacturing of products.

From inception, we have funded our operations from a combination of loans and sales of equity instruments. In 2021 and 2022, we raised aggregate gross proceeds of $5,830,000 and $3,625,000, respectively, from sales of our equity and equity linked securities. In addition, on June 12, 2023, we raised aggregate gross proceeds of $1,000,000 from sales of our shares of common stock and warrants to purchase shares of common stock.

As of September 30, 2023, we had $1,524,000 in cash resources and approximately $561,000 of liabilities, including $559,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the nine months ended September 30, 2023 (in thousands):

	For the nine month ended	
	September 30, 2023	September 30, 2022
	U.S. Dollars (In thousands)	
Net cash used in operating activities	**(2,478)**	(2,596)
Net cash used in investing activities	**(1)**	(57)
Net cash provided by financing activities	**1,000**	3,625

We have experienced operating losses since inception and had a total accumulated deficit of $13,568,000 as of September 30, 2023. We expect to incur additional costs and will require additional capital to realize our business plans. These losses have resulted from significant cash expenditures used in operations. During the nine months ended September 30, 2023 and 2022, our cash used in operations was approximately $2,478,000 and $2,596,000, respectively. As we continue to conduct our business activities, we expect that the cash needed to fund our operations will increase significantly over the next several years, as we will need to continue and intensify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes, and pursue FDA clearance and international regulatory approvals.

We need to obtain additional funding in order to pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements through the first quarter of 2024. Our requirements for additional capital during this period will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our development and engineering efforts to develop the *PressureSafe* and *Nobiotics* devices, clinical studies (to the extent necessary), preliminary testing activities and other related activities;
- the cost, timing and outcomes of regulatory related efforts for commercial sales approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the timing, receipt and amount of sales, profit sharing or royalties, if any, from our potential products;
- the cost of preparing, filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the extent to which we acquire or invest in businesses, products or technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

For the nine months ended September 30, 2023, and as of the date of this report, we assessed our financial condition and concluded that based on our current and projected cash resources and commitments, as well as other factors mentioned above, there is a substantial doubt about our ability to continue as a going concern. We are planning to raise additional capital to continue our operations, as well as to explore additional avenues to increase revenues and reduce expenditures. We cannot be sure that future funding will be available to us on acceptable terms, or at all. Due to the often-volatile nature of financial markets, equity and debt financing may be difficult to obtain.

We may seek to raise any necessary additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights, future revenue streams, or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through private or public equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, as defined by § 229.10(f)(1), we are not required to provide the information required by this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2023, we conducted an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"). The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that the information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods and that such disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our principal Chief Executive Officer and principal Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at reasonable assurance level, as further described below.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2023, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, which could materially affect our business, financial condition, or future results.

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2022, except as noted below.

Our principal executive offices and other significant operations are located in Israel, and, therefore, our results may be adversely affected by political, economic and military instability in Israel, including the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them.

Our executive offices and corporate headquarters are located in Israel. In addition, most of our officers are residents of Israel. Accordingly, political, economic and military and security conditions in Israel and the surrounding region may directly affect our business. Any conflicts, political instability, terrorism, cyberattacks or any other hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations. Ongoing and revived hostilities in the Middle East or other Israeli political or economic factors, could harm our operations.

In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. These attacks resulted in extensive deaths, injuries and kidnapping of civilians and soldiers. Following the attack, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks.

The intensity and duration of Israel's current war against Hamas is difficult to predict, as are such war's economic implications on the Company's business and operations and on Israel's economy in general. These events may be intertwined with wider macroeconomic indications of a deterioration of Israel's economic standing, which may have a material adverse effect on the Company and its ability to effectively conduct some of its operations.

In connection with the Israeli security cabinet's declaration of war against Hamas and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service. Certain of our employees and consultants (and their spouses or partners) in Israel have been called, and additional employees (or their spouses or partners) may be called, for service in the current or future wars or other armed conflicts with Hamas, and such persons may be absent for an extended period of time. As a result, our operations in Israel may be disrupted by such absences, which disruption may materially and adversely affect our business, prospects, financial condition and results of operations.

Following the attack by Hamas on Israel's southern border, Hezbollah in Lebanon has also launched missile, rocket and shooting attacks against Israeli military sites, troops, and Israeli towns in northern Israel. In response to these attacks, the Israeli army has carried out a number of targeted strikes on sites belonging to Hezbollah in southern Lebanon. It is possible that other terrorist organizations, including Palestinian military organizations in the West Bank, as well as other hostile countries, such as Iran, will join the hostilities. Such hostilities may include terror and missile attacks. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Our commercial insurance does not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business. A campaign of boycotts, divestment and sanctions has been undertaken against Israel, which could also adversely impact our business.

Prior to the Hamas attack in October 2023, the Israeli government pursued extensive changes to Israel's judicial system. In response to the foregoing developments, individuals, organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed changes may negatively impact the business environment in Israel including due to reluctance of foreign investors to invest or transact business in Israel as well as to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. The risk of such negative developments has increased in light of the recent Hamas attacks and the war against Hamas declared by Israel, regardless of the proposed changes to the judicial system and the related debate. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors.

ITEM 1. LEGAL PROCEEDINGS

On May 29, 2023, a lawsuit was filed against the Company, the Subsidiary and Mr. Aharon Klein, a Company Director and the Company's Chief Technology Officer in the Tel Aviv District Court of Israel by an individual who provided, on a part time basis, certain consulting services to the Subsidiary between October 2015 through October 2016, prior to the acquisition of the Subsidiary by the Company. The lawsuit alleges breach of contract by the defendants based on non-payment of amounts purportedly owed to the plaintiff in respect of the services rendered, including the market value of the Company's common stock that the plaintiff alleges should have been issued to him in respect of his services. The suit seeks declaratory judgment that the defendants breached certain agreements with the plaintiff and claimed damages in the aggregate amount of approximately $2.1 million based on the current exchange rate between the U.S. Dollar and the Israeli NIS.

The Company believes that the allegations are baseless and without merit. The Company intends to vigorously defend its rights.

Other than as set forth above, the Company is not currently involved in any legal proceedings. However, from time to time we may become involved in various legal proceedings that arise in the ordinary course of business, including actions related to our intellectual property. Although the outcomes of these legal proceedings cannot be predicted with certainty, we are currently not aware of any such legal proceedings that arise in the ordinary course of business, including actions related to our intellectual property. Although the outcomes of these legal proceedings cannot be predicted with certainty, we are currently not aware of any such legal proceedings or claims that we believe, either individually or in the aggregate, will have a material adverse effect on our business, financial condition, or results of operations.

ITEM 6. EXHIBITS

Exhibit Index:

31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer (Principal Executive Officer), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
101. INS	Inline XBRL Instance Document
101. SCH	Inline XBRL Taxonomy Extension Schema
101. CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101. DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101. LAB	Inline XBRL Taxonomy Extension Label Linkbase
101. PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
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 caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IR-Med, Inc.
(Registrant)

By:	*/s/ Oded Bashan* Oded Bashan Chairmen of the Board	By:	*/s/ Sharon Levkoviz* Sharon Levkoviz Chief Financial Officer (Principal Financial and Accounting Officer)
Date:	November 14, 2023	Date:	November 14, 2023

EXHIBIT 31.1

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Oded Bashan, certify that:

I have reviewed this quarterly report on Form 10-Q of IR-Med, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15I and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: * /s/ Oded Bashan*
Oded Bashan, Chairman of the Board

Date: November 14, 2023

EXHIBIT 31.2

Certification Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Sharon Levkoviz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IR-Med, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: *__/s/ Sharon Levkoviz__*
Sharon Levkoviz, Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: November 14, 2023

EXHIBIT 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned Principal Executive Officer of IR-Med, Inc. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Oded Bashan

Oded Bashan, Chairman of the Board

Dated: November 14, 2023

EXHIBIT 32.2

CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned Principal Executive Officer of IR-Med, Inc. (the "Company") hereby certifies to such officer's knowledge that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Sharon Levkoviz
Sharon Levkoviz, Chief Financial Officer
(Principal Financial and Accounting Officer)

Dated: November 14, 2023