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 March 31, 2024; or

□ 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

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 May 13, 2024, there were outstanding 69,975,056 shares of the registrant's common stock, par value $0.001 per share.

IR-MED, INC.
Form 10-Q
March 31, 2024

Interim Unaudited Condensed Consolidated Balance Sheets

	March 31 2024 USD thousands	December 31 2023 USD thousands
Assets		
Current assets		
Cash and cash equivalents	**408**	767
Accounts receivable	**55**	81
Total current assets	**463**	848
Non- current assets		
Long term restricted deposit	**11**	11
Right of use assets	**58**	84
Property and equipment, net	**47**	56
Total non-current assets	**116**	151
Total assets	**579**	999
Liabilities and stockholders' equity (deficiency)		
Current liabilities		
Trade and other payables	**505**	473
Non-current liabilities		
Stockholders' loans	**160**	161
Total liabilities	**665**	634
Stockholders' equity (deficiency)		
Common Stock, par value $0.001 per share, 250,000,000, shares authorized. As of March 31, 2024, and December 31, 2023, 69,931,056 shares were issued.	**69**	69
Additional paid-in capital	**15,341**	15,135
Accumulated deficit	**(15,496)**	(14,839)
Total Stockholders' equity (deficiency)	**(86)**	365
Total liabilities and stockholders' equity (deficiency)	**579**	999

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

Interim Unaudited Condensed Consolidated Statements of Operations

	For the three-months period ended March 31	
	2024	**2023**
	U.S dollars (in thousands)	
Research and development expenses:		
Expenses incurred	**375**	605
Less- government participation	**(180)**	-
Research and development expenses, net	**195**	605
Marketing expenses	**168**	172
General and administrative expenses	**295**	575
Total operating loss	**658**	1,352
Financial income, net	**(1)**	(2)
Loss for the period	**657**	1,350
Basic and dilutive loss per common stock (in dollars)	**(0.01)**	(0.02)

Weighted-average shares in the loss per share computation for the three months ended March 31, 2024 and, 2023 were 69,931,056 and 68,829,424 respectively.

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

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficiency)

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity (deficiency)
	Number of Shares	Amount			
	U.S dollars (in thousands)				
For the three-month period ended March 31, 2024					
Balance as of January 1, 2024	**69,931,056**	**69**	**15,135**	**(14,839)**	**365**
		-		**-**	
Stock-based compensation	**-**	**-**	**206**	**-**	**206**
Loss for the period	**-**	**-**	**-**	**(657)**	**(657)**
Balance as of March 31, 2024	**69,931,056**	**69**	**15,341**	**(15,496)**	**(86)**

	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 March 31, 2023					
Balance as of January 1, 2023	68,808,970	68	12,454	(9,930)	2,592
Stock-based compensation	20,454	*	478	-	478
Loss for the period	-	-	-	(1,350)	(1,350)
Balance as of March 31, 2023	68,829,424	68	12,932	(11,280)	1,720

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

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

Interim Unaudited Condensed Consolidated Statements of Cash Flows

	For the three-month period ended	
	March 31 2024	**March 31 2023**
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	**(657)**	(1,350)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	**206**	478
Depreciation	**9**	4
Accrued financial expenses (income)	**3**	(6)
Decrease (increase) in accounts receivable	**27**	(1)
Increase (decrease) in trade and other payables	**54**	(25)
Net cash used in operating activities	**(358)**	(900)
Effect of exchange rate changes on cash and cash equivalents	**(1)**	1
Net decrease in cash and cash equivalents	**(359)**	(899)
Cash and cash equivalents as at the beginning of the period	**767**	3,002
Cash and cash equivalents as at the end of the period	**408**	**2,103**

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

Note 1 - General

A. Description of Business

IR-Med, Inc. (OTC QB: IRME, hereinafter: the "Parent Company") was incorporated in Nevada in 2007. IR-Med, Inc. was previously named International Display Advertising, Inc. and changed its name to IR-Med, Inc. in January 2021.

The registered office of IR-Med, Inc. and the corporate headquarters and research facility of IR. Med, Ltd. are located in Rosh Pina, Israel. The Parent Company and IR. Med Ltd. (Hereinafter: the "Subsidiary") are at times collectively referred to as the "Company".

On April 9, 2024, the Company's first device, the P*ressureSafe*, decision support device received a U.S. Food and Drug Administration (FDA) listing certification. *PressureSafe* is classified as a Class I device. Following the listing certification of the *PressureSafe* device, the Company has started the preparations for the commercial launch of its first device, the *PressureSafe.* The Company is 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 and reduce the widespread reliance on antibiotics administration, and other interventional options optimizing the delivery of targeted medical services.

On January 25, 2024, the Israel Innovation Authority (the "IIA") approved the Company's proposed program to develop a device for the early detection of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately $1,030,000), which includes an amount equal to 50% grant of the total budget provided at the time of the grant, disbursed in installments over the course of 13 months, in accordance with the project's progress. In consideration for the grant by the IIA, the subsidiary is required to pay royalties at the rate of 3%-5% from the total sales until the repayment date of the full amount of the grant, plus annual interest at the Secured Overnight Financing Rate (SOFR) rate. In addition, the IIA must approve any arrangement whereby the Company seeks to transfer the technology relating to the project, or its development, from Israel.

B. Going Concern

The Company has started the preparations of the commercial launch of its first device, the *PressureSafe,* but does not expect to generate significant revenue until such time as the Company shall have completed the design and development of its initial products candidates and initiates marketing activities for its commercial product. During the three months ended March 31, 2024, the Company incurred losses of $657 thousand and had a negative cash flow from operating activities of $358 thousand. The accumulated deficit as of March 31, 2024 is $15,496 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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Management's plans regarding these matters include continued development and marketing of its products, as well as seeking additional financing arrangements. 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 this first quarter of 2024 Report.

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 of the date of the 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. 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 of the reporting date the Company is unable to assess the extent of the effect of the Iron Swords War on its business.

Note 2 - Interim Unaudited Financial Information

The accompanying unaudited financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("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 for the year ended December 31, 2023.

Note 2 - Interim Unaudited Financial Information (Cont'd)

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 months period ended March 31, 2024 and 2023 and cash flow for the three months period ended March 31, 2024 and 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

Use of Estimates:

The preparation of financial statements in conformity with U.S GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions including fair value of share-based compensation and legal claims. 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 Annual Report for the year ended December 31, 2023.

Note 4 - Stockholders' Loans

On March 1, 2024, the Company and the lenders agreed to extend the repayment date to December 31, 2025.

Shareholders' loans with terms that were amended after the reporting date are considered in determining the classification of debt at the reporting date. Due to agreements reached in 2024 between the shareholders and the Company regarding the repayment date of the loan, the shareholders' loans on March 31, 2024, are classified as non-current liabilities.

Note 5 - Stock Options Plan

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

As of March 31, 2024, the Company awarded to its employees and service providers options to purchase up to 14,096,675 shares of Common Stock, of which options for 7,795,675 shares were at an exercise price of $0.32 per share, options for 5,821,000 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. As of March 31, 2024 options for 13,091,888 shares were vested with a weighted average of exercise of $ 0.41 and the remaining balance has a vesting period ranging between one to three years. The options are exercisable for periods ranging between three to ten years from the vesting date.

	Weighted average of exercise price	Number of options
Outstanding as of beginning of year	$ 0.42	15,544,175
Cancelled	$ 0.32	(1,447,500)
Outstanding as of March 31 ,2024	$ 0.42	14,096,675

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 $206 thousand and $478 thousand during the three months ended March 31, 2024 and 2023 respectively.

The stock-based compensation expenses for the three months ended March 31, 2024 and 2023 were recognized in the statements of operations as follows;

	For the three-month period ended	
	March 31, 2024	**March 31, 2023**
	US Dollars (In thousands)	
Research and development expenses	**23**	45
Marketing expenses	**162**	159
General and administrative expenses	**21**	274
	206	478

Note 5 - 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 three months period ended March 31, 2024 and 2023, using the Black- Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

	For the three-month period ended	
	March 31, 2024	**March 31, 2023**
Dividend yields (see (I) below)	0.0%	0.0%
Share price (in U.S. dollar) (see (II) below)	0.53,0.64	0.53
Expected volatility (see (III) below)	116. % - 84%	114.29% - 95.37%
Risk-free interest rates (see (IV) below)	3.61% - 4.39%	3.61% - 4%
Expected life (in years) (see (V) below)	1.5 - 14.79	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 stock is 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 $1.00, 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 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.

Note 6 - Contingent Liabilities and Commitments

On May 29, 2023, a lawsuit was filed against the Company, the Subsidiary and Mr. Aharon Klein (the "Plaintiff"), a Company Director and the Company's Chief Technology Officer in the Tel Aviv District Court of Israel, by an individual who provided, on part time basis, certain consulting services to the Subsidiary between October 2015 and October 2016, before 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.

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/A for the fiscal year ended December 31, 2023, as filed with the Securities and Exchange Commission, or the SEC, on April 8, 2024. 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.

On February 28, 2024, following financial difficulties, our Board of Directors resolved that the Company's operations would be limited only to critical actions to save funds. Accordingly, the following description of our three product candidates' development and commercialization plans are currently limited and are subject to us being able to raise additional funds to support our operations and to further develop and commercialize our products, which are in various stages of design and development.

We are in the process of developing a cutting-edge infrared spectroscopy and artificial intelligence (AI) analysis technology platform, as a basis for point-of-care decision support devices. The infrared spectroscopy technology allows harmless and non-invasive gathering of bio-information from a patient's blood and tissue. Bioinformation is then analyzed using our AI process to provide healthcare professionals with decision support in the detection and monitoring of various disease conditions.

PressureSafe, our first product based on this platform, is a handheld device designed to revolutionize the early detection of pressure injuries (PIs) affecting skin and underlying tissue. PIs in the U.S. alone account for $26.8 billion in healthcare spending and result in 60,000 deaths annually. *PressureSafe* is expected to contribute to early detection of PIs, regardless of patient skin tone. This will drive equitable healthcare and help reduce the toll and cost of PIs. We plan to launch *PressureSafe* as a decision support system (DSS) tool for caregivers in hospitals, nursing homes, and home-care companies. On April 9, 2024, the *PressureSafe* decision support device received a U.S. Food and Drug Administration (FDA) listing certification. *PressureSafe* is classified as a Class I device and is exempt from 510(k) premarket submission. We are currently working on completing the development of the commercial version of the *PressureSafe* device, planned to be launched during 2024, following the listing under the FDA.

We plan to commence a clinical trial in the center of Israel's leading diabetes clinic.

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 that consequently does not require antibiotic treatment.

Our technology platform utilizes 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 at 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 solutions utilizing our proprietary platform for the pre-emptive diagnosis of PIs and diabetic foot ulcers. Our current business plan focuses on two principal medical devices:

1. *PressureSafe*, a handheld optical monitoring device that is being developed to support early detection of PIs to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement. We have started preparations for a commercial launch for this device, subject to us being able to raise additional funds.

2. *DiaSafe,* a handheld optical monitoring device that is being developed to support early detection of diabetic foot ulcers in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole and diabetes. This device is currently under development.

Distribution Agreement

On October 7, 2022, we entered into an exclusive Distribution and License Agreement, or the Distribution Agreement, with PI Prevention Care LLC, a Delaware limited liability company, or the Distributor, under which the Distributor received exclusive royalty-bearing rights to promote, market and sell solely in the United States our *PressureSafe* monitoring device.

The Distributor is a recently formed Delaware entity comprised of persons and other entities including Company shareholders, who are active in the markets relating to senior care facilities, hospitals, home care centers, and hospital equipment distributors, among others, throughout the United States and who are familiar with and have wide experience in addressing and responding to the needs of these medical care organizations.

Under the Distribution Agreement, the Distributor is solely responsible for the distribution, marketing, and sales of the *PressureSafe* and its accompanying components and agreed to undertake all commercially reasonable efforts to establish the necessary distribution and sales network for the Products by not later than the date on which the Company shall have received all regulatory and other clearance required to launch the commercialization of the *PressureSafe* Solution (such Date being the "Commercial Launch Date"). Before the Commercial Launch Date, the Distributor is to invest such resources as is reasonable such that upon the occurrence of the Commercial Launch Date there will be a commercially reasonable distribution network in place for the immediate marketing of the Product.

The Distribution Agreement provides for the payment of annual licensing fees. The Distribution Agreement also specifies the prices of each component of the Products payable to the Company and also provides for minimum annual purchase requirements of Product components to maintain exclusivity. If for whatever reason the Distributor does not comply with the minimum purchase requirements in any year, the Distributor can continue to have a non-exclusive license and distribution rights in the United States if the Distributor pays the annual license fee.

Subject to the compliance by the Distributor of its obligation under the Distribution Agreement, including the purchase by the Distributor of minimum annual purchase requirements of the components of the Products, the Distribution Agreement continues in effect for a term of 13 years following the Commercial Launch Date. At the end of the initial three- and eight-year periods, the parties are to enter into good faith negotiations as to the pricing of the Products and the minimum purchase quantities for the subsequent period. The Distributor also agreed to not distribute any products that compete with the Products.

Manufacturing

We do not own or operate manufacturing facilities. While we plan to depend on third-party contract manufacturers for device manufacturing, we plan to perform the final assembly, quality control, and release of finished goods in our facilities.

Manufacturers of our products are required, among other things, to comply with applicable FDA/EMA manufacturing requirements contained in the FDA/EMA's Quality System Regulation (QSR). The QSR requires manufacturing quality assurance and quality control as well as the corresponding maintenance of records and documentation.

Major changes to the device generally require regulatory approval before being implemented (e.g., adding new indications and additional labeling claims, etc.).

Under FDA Medical Device Reporting (MDR) regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. Discovery of problems with a product after product release may result in a restriction on a product or manufacturer, including withdrawal of the product from the market.

We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates if they are approved. We intend to enter into contract manufacturing agreements and one or more backup manufacturers for the commercial production of our product candidates when they are near potential approval.

Distribution and Revenue Generation

We intend to establish sales and marketing structures and strategic partnerships in the United States, U.K., and Europe to support all of our product candidates.

The target market for our *PressureSafe* device is relevant healthcare settings (*i.e.*, hospitals, senior care facilities, home care companies, etc.), nursing homes, and a growing segment of long-term home care caregivers. Towards that end, in the third quarter of 2022, we began preparations in anticipation of the commercialization of *PressureSafe* in the United States in 2024. A distribution agreement was entered into with PI Prevention Care LLC, a newly formed entity focused on marketing to the senior care facility, hospital, and homecare markets. The Distributor, which received exclusive rights for *PressureSafe* distribution across the United States, includes personnel who have many years of experience in addressing and responding to the needs of these types of organizations. Under the terms of the Agreement which were publicly disclosed, to maintain exclusivity, the Distributor is obligated to comply with minimum purchase requirements of the device and accompanying disposables.

In April 2024, we received the appropriate sales approvals by the FDA, and we expect the marketing will be done with local partners who have the relevant abilities and connections in each territory such partners will ask to sell the products. Since each country has its specific healthcare system, a local partner (one or more) will be chosen to address the specific market needs in terms of regulation, technical support, etc. Pricing will be determined by the local partner, taking into account all overhead expected costs, regulation requirements, and reimbursement methods.

The *DiaSafe* once developed, will be marketed pending our receipt of the appropriate sales approvals. We expect the marketing will be done with local partners who have the relevant abilities and connections per each relevant distribution territory. Since each country has its specific healthcare system, a local partner (one or more) will be chosen to address the specific market needs in terms of regulations and technical support. Pricing will be determined by the local partner, taking into account all overhead expected costs, regulation requirements, and reimbursement methods.

In both the *PressureSafe* and the *DiaSafe* devices, the revenue stream is expected to be generated mainly from the disposables and *PressureSafe* solution as a service (PSaaS) that are needed for the proper operation of the device, while the device itself is likely to be given under lease agreements. It is envisioned that the disposable component will be mass-produced.

It is expected that market penetration will be achieved through original equipment manufacturing agreements with one of several large medical device companies already selling to the target market. At the current time, we have no commitments from any such distributors or original equipment manufacturing partners.

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 the next generation of our *PressureSafe* device and develop the *DiaSafe,* device. 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 the exchange rate derived from the re-measurement of monetary balance sheet items denominated in non-dollar currencies. Other financial expenses include bank fees and interest on stockholders' loans.

Results of Operations

Comparison of the Three Months Ended March 31, 2024, to the Three Months Ended March 31, 2023

	For the three months ended March 31,	
	2024	**2023**
	U.S dollars (in thousands)	
Research and development expenses, net	**195**	605
Marketing expenses	**168**	172
General and administrative expenses	**295**	575
Total operating expenses	**658**	1,352
Financial income, net	**(1)**	(2)
Loss for the period	**657**	1,350

Revenues. During the three-month period ended March 31, 2024, and 2023, we did not record any revenues from operations.

Research and Development Expenses. Research and development expenses consist of salaries and related expenses, consulting fees, service providers' costs, and overhead expenses. Research and development expenses decreased from $605,000 during the three months ended March 31, 2023, to $195,000 during the corresponding three-month period in 2024. The decrease in the 2024 period resulted primarily from a decrease in the use of third-party contractors for further research and development activities due to the completion of the development of the *PressureSafe* device, proceeds of a grant from the Israel Innovation Authority (the "IIA"), 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 decreased from $172,000 during the three months ended March 31, 2023, to $168,000 during the corresponding three-month period in 2024. The decrease in marketing expenses resulted primarily from the reduction in professional services, partially offset by an increase in non-cash expenses attributable to stock-based compensation to service providers.

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 decreased from $575,000 during the three months ended March 31, 2023, to $295,000 in the corresponding three-month period in 2024. The decrease in general and administrative expenses resulted primarily from a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers, a reduction in payroll expenses and a reduction in professional services.

Loss. Loss for the three months ended March 31, 2023, was $1,350,000 compared to $657,000 for the corresponding three-month period in 2024. The decrease in net loss is primarily attributable to a decrease in use of third-party contractors for further research and development activities due to the completion of the development of the *PressureSafe* device, proceeds of a grant from the IIA, a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers and a reduction in payroll expenses and professional services.

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 March 31, 2024, we had $408,000 in cash resources and approximately $665,000 of liabilities, including $505,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the three months ended March 31, 2024 (in thousands):

	For the three months ended	
	March 31, 2024	**March 31, 2023**
	US Dollars (In thousands)	
Net cash used in operating activities	**(358)**	(900)

We have experienced operating losses since inception and had a total accumulated deficit of $15,484,000 as of March 31, 2024. We expect to incur additional costs and will require additional capital to realize our business plans. These losses have resulted in significant cash used in operations. During the three months ended March 31, 2024, and 2023, our cash used in operations was approximately $358,000 and $900,000, respectively. We 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 for our additional products, and international regulatory approvals. As we continue to conduct these activities, we expect the cash needed to fund operations to increase significantly over the next several years.

We will need to obtain additional funding to pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we will 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 second 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 three months ended March 31, 2024, 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 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 the 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 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

A smaller reporting company, as defined by § 229.10(f)(1), is not required to provide the information required by this Item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of March 31, 2024, 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 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 March 31, 2024, our principal Chief Executive Officer and principal Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a 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 that ended March 31, 2024, there were no changes in our internal control over financial reporting that have materially affected or are reasonably likely to affect, our internal control over financial reporting materially.

PART II—OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On May 29, 2023, a lawsuit was filed against the Company, the Subsidiary, and Mr. Aharon Klein, or the Plaintiff, 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, before 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 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 1A. RISK FACTORS

An investment in the Company's Common Stock involves several very significant risks. You should carefully consider the risk factors included in the "Risk Factors" section of our Annual Report on Form 10-K/A for the year ended December 31, 2023, as filed with the SEC on April 8, 2024, in addition to other information contained in our reports and in this quarterly report in evaluating the Company and its business before purchasing shares of our Common Stock.

ITEM 2. UNREGISTERED SALES OF SECURITIES AND USE OF PROCEEDS

N/A

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

N/A

ITEM 5. OTHER INFORMATION:

N/A

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)

* Filed herewith

** Furnished herewith

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/ Aharon Klein*	By:	*/s/ Sharon* Levkoviz
	Aharon Klein Interim Chief Executive Officer (Principal Executive Officer)		Sharon Levkoviz Chief Financial Officer (Principal Financial and Accounting Officer)
Date:	May 13, 2024	Date:	May 13, 2024

EXHIBIT 31.1

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

I, Aharon Klein, 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/ Aharon Klein*
Aharon Klein, Interim Chief Executive Officer
(Principal Executive Officer)

Date: May 13, 2024

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: May 13, 2024

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 March 31, 2024 (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/ Aharon Klein
Aharon Klein, Interim Chief Executive Officer
(Principal Executive Officer)

Dated: May 13, 2024

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 March 31, 2024 (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: May 13, 2024