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, 2023; 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	
(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 15, 2023, there were outstanding68,829,424 shares of the registrant's common stock, par value $0.001 per share.

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Interim Unaudited Condensed Consolidated Balance Sheets

	March 31 2023	December 31 2022
	U.S dollars (in thousands)	
Assets		
Current assets		
Cash and cash equivalents	**2,103**	3,002
Accounts receivable	**56**	55
Total current assets	**2,159**	3,057
Non- current assets		
Long term restricted deposit	**11**	11
Operating lease right of use assets	**136**	155
Property and equipment, net	**67**	71
Total non-current assets	**214**	237
Total assets	**2,373**	3,294
Liabilities and Stockholders' equity		
Current liabilities		
Trade and other payables	**468**	500
Stockholders' loans	**159**	162
Total current liabilities	**627**	662
Non-current liabilities		
Long term lease liability	**26**	40
Total liabilities	**653**	702
Stockholders' Equity		
Common Stock, par value $0.001 per share, 250,000,000, shares authorized. as of March 31, 2023 and December 31, 2022; 68,829,424 and 68,808,970 shares issued, respectively.	**68**	68
Additional paid-in capital	**12,932**	12,454
Accumulated deficit	**(11,280)**	(9,930)
Total Stockholders' equity	**1,720**	2,592
Total liabilities and stockholders' equity	**2,373**	3,294

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-month period ended March 31	
	2023	2022
	U.S dollars (in thousands)	
Research and development expenses	**605**	477
Marketing expenses	**172**	51
General and administrative expenses	**575**	325
Total operating loss	**1,352**	853
Financial income, net	**(2)**	(4)
Loss for the period	**1,350**	849
Basic and dilutive loss per common stock (in dollars)	**(0.020)**	(0.013)

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

	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

	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, 2022					
Balance as of January 1, 2022	64,601,649	64	7,503	(5,196)	2,371
Stock-based compensation	-	-	53		53
Loss for the period	-	-	-	(849)	(849)
Balance as of March 31, 2022	64,601,649	64	7,556	(6,045)	1,575

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 2023	March 31 2022
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	**(1,350)**	(849)

Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	**478**	53
Depreciation	**4**	3
Accrued financial income	**(6)**	(2)
Increase in accounts receivable	**(1)**	(80)
(Decrease) increase in trade and other payables	**(25)**	121
Net cash used in operating activities	**(900)**	(754)
Cash flows from investing activities		
Purchase of property and equipment	**-**	(11)
increase in long term deposit	**-**	(9)
Net cash used in investing activities	**-**	(20)
Effect of exchange rate changes on cash and cash equivalents	**1**	(2)
Net Decrease in cash and cash equivalents	**(899)**	(776)
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	**2,103**	2,039
Supplemental disclosure of cash flow information:		
Non-cash transactions:		
(Decrease) increase in non-current assets from recording of rights of use assets	**-**	160
Increase (decrease) in non-current liabilities from recording of liability of lease agreements	**-**	(160)

The accompanying notes are an integral part of these interim unaudited condensed consolidated 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 "Parent Company") was incorporated in Nevada in 2007 and is a holding company.

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 Company is a development stage medical device company developing its technology through its Subsidiary and is utilizing Infra-Red light spectroscopy (IR) combined with 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 reducing the widespread reliance on antibiotics administration, and other interventional options optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

B. Going Concern

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 the product. During the three months ended March 31, 2023, the Company has incurred losses of US$1,350 thousand and had a negative cash flow from operating activities of US$900 thousand. The accumulated deficit as of March 31, 2023 is US$ 11,280 thousand.

Management's plans regarding these matters include continued development and marketing of its 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 2023 Report.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

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, 2022.

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 month period ended March 31, 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 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 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 Annual Report for the year ended December 31, 2022.

Note 4 - Stock options plan

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

As of March 31, 2023, the Parent Company awarded to its employees and service providers options to purchase up to 14,143,842 shares of Common Stock, of which options for 8,687,842 shares were at an exercise price of US$0.32 per share, options for 4,776,000 shares were at an exercise price of US$0.58 per share, options for 480,000 shares were at an exercise price of US$0.01 per share and options for 200,000 shares

Note 4 - Stock options plan (Cont'd)

were at an exercise price of $0.64 per share. As of March 31, 2023 options for 9,494,372 shares were vested and the remaining balance has a vesting period ranging between one to three years. The options are exercisable for periods ranging betweenthree to ten years from the vesting date.

The grant was approved following the adoption of the 2020 incentive stock plan (hereinafter the "Plan") by the Parent Company on December 23, 2020 and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021. The Group recorded in the statement of operations a non-cash expense of $478 thousands and $53 thousands during the three months ended March 31, 2023 and 2022 respectively.

The stock-based compensation expenses for the three months ended March 31, 2023 and 2022 were recognized in the statements of operations as follows;

	For the three-month period ended	
	March 31, 2023	March 31, 2022
	US Dollars (In thousands)	
Research and development expenses	**45**	21
Marketing expenses	**159**	-
General and administrative expenses	**274**	32
	478	53

The following table sets forth information about the weighted-average fair value of options granted to employees and service providers during the three month periods ended March 31, 2023 and 2022, 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, 2023	March 31, 2022
Dividend yields (see (I) below)	0.0%	0.0%
Share price (in U.S. dollar) (see (II) below)	0.53	0.26
Expected volatility (see (III) below)	114.29% - 95.37%	82.77% - 142.57%
Risk-free interest rates (see (IV) below)	3.61% - 4%	0.18% - 1.7%
Expected life (in years) (see (V) below)	5 - 14.79	1.5 - 14.79

Note 4 - Stock options plan (Cont'd)

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

II. The Parent-Company's common stocks are quoted on the Over the Counter ("OTC"). However, the Group considers its share price as it is traded on OTC to not be an appropriate representation of fair value, since it is not traded on an active market. The Group determined that the market is inactive due to low level of activity of the Parent 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 Parent-Company's Common Stock has been determined based on the April 2021 and July 2022 Private placement units of Common Stock and Warrants at a per unit purchase price of $0.64 and $0.88 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 Group 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 Group 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.

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 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

IR-Med is 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, which we call *PressureSafe*, is a handheld optical monitoring device that is being developed to support early detection of pressure injuries (PI) to the skin and underlying tissue, regardless of skin tone and which calibrated personally to each patient's skin, primarily caused by prolonged pressure associated with bed confinement. Our skin-device-interphase development of personalized medical devices allows high accuracy readings from the human body in a non-invasive method, that may provide caregiver the optimal decision support-system in cases where uncertainties disturb physicians in their decision processes. We plan to launch 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, which we call *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 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 make 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 the task.

The global diagnostics market is driven in large part 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. We believe that offering additional Decision Support Systems (DSS) tools may improve diagnoses and outcomes through the adoption of AI-based decision support tools.

Our initial focus is on the development of DSS solutions utilizing our proprietary platform for the pre-emptive diagnosis of pressure injuries (PI) 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 (PI) 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*. In August 2022, IR Med. Ltd., entered into an agreement with an Israeli boutique industrial design company specializing in the design of medical devices and diagnostic products servicing a broad array of companies, including large multinational companies, for the design of the *PressureSafe* device in its advanced configuration, which incorporates preliminary results from a usability study currently being performed in Israel, including feedback from healthcare professionals. In February 2023, our subsidiary IR-Med Ltd. entered into an agreement with Rabin Medical Center (**RMC**) in Israel to perform a usability study, as an additional study center to the current study that we have been performing at Beit-Rivka, a large geriatrics hospital in Israel. The agreement is to conduct a usability study of our proprietary and patent protected "PressureSafe" device, which we plan to launch as a decision support system (DSS) tool for care givers in Hospitals, Nursing homes and Home-Care companies.

We are currently working on completing the development of the commercial version of the *PressureSafe* device, planned to be launched during 2023, pending FDA clearance.

Distribution Agreement

In the third quarter of 2022, we began preparations in anticipation of commercialization of *PressureSafe* in the United States pending regulatory approvals. On October 7, 2022, IR. Med, Ltd. and PI Prevention Care LLC, a Delaware limited liability company (the "Distributor") entered into an exclusive Distribution and License Agreement (the "Distribution Agreement") pursuant to 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, 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 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"). Prior to 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 in order 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 thirteen years following the Commercial Launch Date. At the end of the initial three and eight year period, 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.

Distribution and Revenue Generation

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

The target markets for our PressureSafe device are relevant Health care setting (i.e., hospitals, senior care facilities, home care companies etc.), nursing homes and a growing segment of long terms home care givers. Towards that end, in third quarter of 2022, we began preparations in anticipation of commercialization of *PressureSafe* in the United States during 2023, pending regulatory approvals.

Once we receive the appropriate sales approvals, we expect the marketing will be done with local partners who have the relevant abilities and connections per each territory the company will ask to sell the products at. Since each country has its own specific healthcare system, a local partner (one or more) will be chosen to address the specific market needs- in terms of regulation, technical support and so on. Pricing will be determined by the local partner, taking in account all overhead expected costs, regulation requirements and reimbursement methods.

Nobiotics' target users will be pediatricians, family doctors and Ear, Nose and Throat (ENT) doctors. The distribution of the Nobiotics is expected to be carried out by companies who are suppling devices and disposables to the target audience.

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

It is expected that market penetration for *Nobiotics* will be achieved through OEM 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 OEM 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 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 include 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 and 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 long term loans.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 to the Three Months Ended March 31, 2022

	For the three months ended March 31,	
	2023	2022
	U.S dollars (in thousands)	
Research and development expenses	**605**	477
Marketing expenses	**172**	51
General and administrative expenses	**575**	325
Total operating expenses	**1,352**	853
Financial income, net	**(2)**	(4)
Loss for the period	**1,350**	849

Revenues. During the three-month period ended March 31, 2023 and 2022, we did not recorded any revenues from operation.

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 increased from $ 477,000 during the three months ended March 31, 2022 to $605,000 during the corresponding three month period in 2023. The increase in 2023 period resulted primarily from the recruitment of employees, 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 respecting stock based compensation to employees and service providers.

Marketing Expenses – Marketing expenses consist primarily of salaries and professional services. Marketing expenses increased from $51,000 during the three months ended March 31, 2022 to $172,000 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.

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 expense increased from $325,000 during the three months ended March 31, 2022 to $575,000 in the corresponding three-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.

Loss. Loss for the three months ended March 31, 2023 was $1,350,000 compared to $849,000 for the corresponding three month period in 2023. The increase in net loss is primarily attributable to non-cash expenses attributable 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.

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.

As of March 31, 2023, we had $2,103,000 in cash resources and approximately $653,000 of liabilities, including of $627,000 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, 2023 (in thousands):

	For the three months ended	
	March 31, 2023	March 31, 2022
	US Dollars (In thousands)	
Net cash used in operating activities	(900)	(754)
Net cash used in investing activities	-	(20)

We have experienced operating losses since inception and had a total accumulated deficit of $11,280,000 as of March 31, 2023. 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, 2023 and 2022, our cash used in operations was approximately $900,000 and $754,000, 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 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 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 fourth quarter of 2023. 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, 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 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 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

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, 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 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 March 31, 2023, our principal executive officer and principal 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 March 31, 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 1. LEGAL PROCEEDINGS

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 a number of very significant risks. You should carefully consider the risk factors included in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2022, as filed with the SEC on March 29, 2023, 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. There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2022.

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:

None

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)

*** Portion of the Exhibit have been omitted.

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/ Moshe Gerber* Moshe Gerber Chief Executive Officer (Principal Executive Officer)	By:	*/s/ Sharon* Levkoviz Sharon Levkoviz Chief Financial Officer (Principal Financial and Accounting Officer)
Date:	May 15, 2023	Date:	May 15, 2023

EXHIBIT 31.1

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

I, Moshe Gerber, 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/ Moshe Gerber*
Moshe Gerber, Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 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: May 15, 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 March 31, 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/ Moshe Gerber
Moshe Gerber, Chief Executive Officer
(Principal Executive Officer)

Dated: May 15, 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 March 31, 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: May 15, 2023