

**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, 2025

☐ 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 (State or other jurisdiction of incorporation or organization)	84-4516398 (I.R.S. Employer Identification No.)
ZHR Industrial Zone Rosh Pina Israel (Address of principal executive offices)	1231400 Zip Code

+ 972-4-655-5054

(Registrant's telephone number, including area code)

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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, 2025, there were outstanding 72,018,144 shares of the registrant's common stock, par value \$0.001 per share.

IR-MED, INC.
Form 10-Q
March 31, 2025

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Interim Unaudited Condensed Consolidated Balance Sheets

		March 31 2025	December 31 2024
		USD thousands	USD thousands
	Note		
Assets			
Current assets			
Cash and cash equivalents		51	129
Accounts receivable		30	76
Total current assets		81	205
Non- current assets			
Long term restricted deposits		11	11
Property and equipment, net		32	35
Total non-current assets		43	46
Total assets		124	251
Liabilities and stockholders' deficit			
Current liabilities			
Trade and other payables	5	428	388
Stockholders' loans		158	157
Convertible loans of related parties	4	31	-
Total Current Liabilities		617	545
Total liabilities		617	545
Contingent liabilities	8		
Stockholders' deficit			
Common Stock, par value \$0.001 per share, 600,000,000, shares authorized. As of March 31, 2025, and December 31, 2024, 72,008,144 and 71,008,144 shares were issued and outstanding, respectively.			
		72	70
Additional paid-in capital		16,946	16,374
Accumulated deficit		(17,511)	(16,738)
Total Stockholders' deficit		(493)	(294)
Total liabilities and stockholders' deficit		124	251

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	
	2025	2024
	U.S dollars (in thousands)	
Research and development expenses:		
Expenses incurred	64	375
Less- government participation	(41)	(180)
Research and development expenses, net	23	195
Marketing expenses	2	168
General and administrative expenses	228	295
Total operating loss	253	658
Financial (income) expense, net	520	(1)
Loss for the period	773	657
Basic and dilutive loss per common stock (in dollars)	(0.01)	(0.01)

Weighted-average number of shares in the loss per share computation for the three months ended March 31, 2025 and three months ended March 31, 2024 were 71,258,144 and 69,931,056, 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' Deficit

	Common Stock		Additional		Total
	Number of		paid-in	Accumulated	Stockholders'
	Shares	Amount	Capital	deficit	deficit
			U.S dollars (in thousands)		
For the three-month period ended March 31, 2025					
Balance as of January 1, 2025	71,008,144	70	16,374	(16,738)	(294)
Stock-based compensation	-	-	54	-	54
Issuance of Shares	1,000,000	2	518	-	520
Loss for the period	-	-	-	(773)	(773)
Balance as of March 31, 2025	72,008,144	72	16,946	(17,511)	(493)
	Common Stock		Additional		Total
	Number of		paid-in	Accumulated	Stockholders'
	Shares	Amount	Capital	deficit	deficit
			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)

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	March 31
	2025	2024
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	(773)	(657)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	54	206
Depreciation	3	9
Non-cash financial expenses	520	3
Decrease in accounts receivable	46	27
Increase in trade and other payables	40	54
Net cash used in operating activities	(110)	(358)
Cash flows from Financing activities		
Proceeds from short-term loan	39	-
Repayment of short-term loan	(39)	-
Issuance of convertible loans	31	-
Net cash provided from financing activities	31	-
Effect of exchange rate changes on cash and cash equivalents	1	(1)
Net decrease in cash and cash equivalents	(78)	(359)
Cash and cash equivalents as at the beginning of the period	129	767
Cash and cash equivalents as at the end of the period	51	408

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. 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 PressureSafe™, decision support system, received a U.S. Food and Drug Administration (“FDA”) listing certification. PressureSafe™ is classified as a Class I device, decision support system. Following the listing certification of the PressureSafe™ device, the Company has started usability studies and 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 assessing various biomarkers and molecules in the blood and in human tissue in real-time. The second product candidate, DiaSafe™ which is currently under development is a non-invasive, user friendly device which is designed to address the medical needs of large and growing target patient groups by offering assessment of Diabetic Foot Ulcer (“DFU”) before skin breakage, which is expected to reduce healthcare expenses and better patient care.

B. Going Concern

The Company is starting the preparations of the commercial launch of its first device, the PressureSafe™, and does not expect to generate significant revenue until such time as the Company will start the commercialization of the PressureSafe™ and shall complete the design and development of its other product candidates. During the three months ended March 31, 2025, the Company incurred losses of \$773 thousand and had a negative cash flow from operating activities of \$110 thousand. The accumulated deficit as of March 31, 2025 is \$17,511 thousand.

Based on the current expected level of operating expenditures, the Company’s cash resources as of March 31, 2025 will be sufficient to meet its operating and capital needs through the second quarter of 2025 and shall not be sufficient for a period of at least 12 months from the issuance of these consolidated financial statements. Management’s plans regarding these matters include continued development and marketing the Company’s products, as well as seeking additional financing arrangements. Although management continues to pursue these plans, in the event financing is not obtained, the Company may pursue additional cost cutting measures or may be required to delay, reduce the scope of, or eliminate any of its development programs, these events could have a material adverse effect on its business. These factors raise substantive doubt about the Company ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

C. Iron Swords war impact

Further the described in note 1C to the Company’s annual report for the year ended December 31, 2024, the Company did not experience significant changes in its activities from the continuation of the war during the reporting period. However, the Company’s management continues to believe that the general conditions have brought further difficulties in management’s efforts to seek additional financing arrangements.

Although the Company’s business and operations have not been materially impacted as of the date of these financial statements, any escalation or expansion of the war could have a negative impact on both global and regional conditions and may adversely affect the Company’s business, financial condition, and results of operations.

Since this is an event that is not under the control of the Company and matters such as the fighting continuing or stopping may affect the Company’s assessments, as at the reporting date the Company is unable to assess the extent of the effect of the Iron Swords War on its business.

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 for the year ended December 31, 2024.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

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 and cash flow for the three months period ended March 31, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025.

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, 2024.

Note 4 - Significant Events During the Reporting Period

1. In January 2025, in light of the Company's cash position, the Company and its two officers agreed to reduce their salaries for the months of January and February 2025. According to this agreement, their salaries will range between NIS 6,000 (approximately \$1,644) and NIS 10,000 (approximately \$2,740) per month.
2. On February 16, 2025, the Company obtained a short-term loan of NIS 140,000 (approximately \$39,000) from Bank Hapoalim. The loan bears an annual interest rate of 9% and is repayable in two equal installments on April 30, 2025, and May 31, 2025. In March 2025, the Company repaid the loan.
3. On March 11, 2025 the Company entered into an Equity Purchase Agreement with Williamsburg Venture Holdings, LLC, a Nevada limited liability company (the "Investor"), pursuant to which the Investor agreed to invest up to Fifteen Million Dollars (\$15,000,000) over a 24-month period (unless otherwise determined therein) in accordance with the terms and conditions of an Equity Purchase Agreement, dated as of March 11, 2025, by and between the Company and the Investor (the "Equity Purchase Agreement"). In connection with the Equity Purchase Agreement, the parties also entered into a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which the Company agreed to register with the Securities and Exchange Commission (the "SEC") the Company's common stock issuable under the Equity Purchase Agreement. Pursuant to the terms of the Equity Purchase Agreement, the Investor agreed to accept a put notice of up to \$500,000 upon a registration statement being declared effective by the SEC.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 4 - Significant Events During the Reporting Period (Cont'd)

During the term of the Equity Purchase Agreement, the Company shall be entitled to put to the Investor, and the Investor shall be obligated to purchase, such number of shares of common stock of the Company (such shares, the "Put Shares") at such price as determined in accordance with the Equity Purchase Agreement. The per share purchase price for the Put Shares shall be equal to 90% of the market price defined as the average of the two (2) lowest Volume-Weighted Average Price (VWAP) for the five (5) consecutive trading days immediately preceding the relevant Clearing Date (defined therein), as reported by Bloomberg Finance L.P. or other reputable source. Further, in consideration of the Company's Put rights, and subject to the terms of the Equity Purchase Agreement, the Investor was issued 1,000,000 shares of the Company's common stock. Pursuant to the Equity Purchase Agreement, the Investor may not acquire at any point, more than 9.99% of the outstanding common stock of the Company.

The fair value of the 1,000,000 shares issued at the date of the agreement in the amount of \$520 thousand was recorded as financial expenses in the statement of operations.

4. Effective March 26, 2025, the Company entered into a Note Purchase Agreement (the "Purchase Agreement") with Mr. Ran Ziskind, Mr. Yaniv Cohen, and Mr. Oded Bashan for an aggregate amount of \$31,200. Pursuant to the Purchase Agreement, the Company issued unsecured convertible promissory notes (the "Notes") to Mr. Ziskind, Mr. Cohen, and Mr. Bashan in the principal amount of \$10,400 for each Note. The Notes bear simple interest at a rate of 9% per annum and mature on the earlier of (i) March 26, 2026, or (ii) upon the completion by the Company of an equity or debt financing generating gross proceeds of at least \$100,000. The Notes are convertible, at the election of the holder, on the maturity date into shares of the Company's common stock at a price per share equal to 85% of the closing price of the common stock on the applicable trading market as of the maturity date. The Notes are subject to customary events of default, upon which the outstanding principal and accrued interest may become immediately due and payable. The Company may not prepay the principal amount without the consent of a majority of the holders of all outstanding Notes, though accrued interest may be paid at any time.

5. On March 31, 2025, the Company's board of directors decided to approve the extension of the expiration date of 3,636,634 warrants until June 30, 2025. This extension is subject to the approval of the warrants holders.

Note 5 - Trade and Other Payables

	March 31 2025	December 31 2024
	US Dollars (In thousands)	
Trade payables	50	58
Accrued expenses	206	188
Payroll and related	28	28
Related Parties	144	114
	428	388

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 6 – Segment Information

This segment structure reflects the financial information and reports used by the Company’s management, specifically its Chief Operating Decision Maker (“CODM”), to make decisions regarding the Company’s business, including resource allocations and performance assessments, as well as the current operating focus in compliance with Accounting Standards Codification (“ASC”) 280, Segment Reporting.

The Company has one operating and reportable segment, *PressureSafe™ & DFU* device activity. The *PressureSafe™ & DFU* device utilizes IR spectroscopy combined with an 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.

To date, the Company has not generated revenue. The Company expects to continue to incur significant expenses and operating losses as its product matures for distribution.

The accounting policies of the Company segment are the same as those used in the preparation of its financial statements. The CODM assesses the performance of its operations based on net loss.

The measure of segment assets is reported on the balance sheet as total assets.

The following table presents information about the Company’s single reportable segment by significant expenses categories regularly reviewed by the CODM for the three months ended March 31, 2025, and March 31, 2024:

	For the three months ended March 31	
	2025	2024
	US Dollars (In thousands)	
Research and development expenses		
Salaries and related expenses	29	187
Subcontractors	4	121
Materials	7	-
Usability study	5	14
Other expenses	13	32
Less- government grants	(41)	(180)
Research and development expenses, net	17	174
Marketing expenses	1	2
General and administrative expenses		
Salaries and related expenses	21	54
Professional expenses	123	165
Rent and Maintenance	25	32
Other expenses	9	16
Total General and administrative expenses	178	267
Financial expenses (income), net	520	(1)
Depreciation	3	9
Stock-based compensation	54	206
Segment net loss	773	657

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 7 - Stock Options Plan

On December 23, 2020, the Company's board of directors approved, and its shareholders adopted a share-based compensation plan ("2020 Incentive Stock Plan") for future grants by the Parent Company. On April 29, 2021, the Company adopted a sub plan (the "Israeli appendix"). On September 27, 2023, the Company's Board approved a further amendment to the 2020 Incentive Stock Plan to increase the number of shares authorized for issuance of awards under the 2020 Incentive Stock Plan from 16,000,000 shares to an aggregate of 17,500,000 shares of common stock. The holders of a majority of the Company's voting stock approved such an increase.

As of March 31, 2025, the Company awarded to its employees and service providers options to purchase up to 14,922,175 shares of Common Stock, of which options for 7,535,675 shares were at an exercise price of \$0.32 per share, options for 7,131,000 shares were at an exercise price of \$0.58 per share, options for 255,500 shares were at an exercise price of \$0.01 per share. As of March 31, 2025 options for 13,243,550 shares were vested with a weighted average of exercise of \$ 0.42 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.

	For the three-month period ended			
	March 31, 2025		March 31, 2024	
	Weighted average of exercise price	Number of options	Weighted average of exercise price	Number of options
Outstanding as of the beginning of the period	\$ 0.51	15,072,175	\$ 0.42	15,544,175
Granted	\$ -	-	\$ -	-
Forfeited	\$ 0.58	(150,000)	\$ 0.32	(1,447,500)
Outstanding as of the end of period	\$ 0.44	<u>14,922,175</u>	\$ 0.42	<u>14,096,675</u>

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 \$574 thousand and \$206 thousand during the three months ended March 31, 2025 and 2024 , respectively.

The stock-based compensation expenses for the three months ended March 31, 2025 and March 31, 2024 were recognized in the statements of operations as follows;

	For the three-month period ended	
	March 31, 2025	March 31, 2024
	US Dollars (In thousands)	
Research and development expenses	7	23
Marketing expenses	1	162
General and administrative expenses	<u>46</u>	<u>21</u>
	<u>54</u>	<u>206</u>

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 8 - Contingent Liabilities and Commitments

On May 29, 2023, a lawsuit was filed against the Company, the Subsidiary and Mr. Aharon Klein, a Company Director and the Company's Chief Technology Officer in the Tel Aviv District Court of Israel, by an individual who provided, on 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 lawsuit seeks a 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.

On November 27, 2024, the first pre-trial hearing in the case was held. After directing questions for clarification to the parties, the honorable court referred the parties to mediation. Mediation sessions were held in January 2025 and April 2025. The parties informed the honorable court on April 23, 2025, of the failure of the mediation process.

The Company records a provision in its financial statements to the extent that it concludes that 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 the 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.

Note 9 – Subsequent Events

On April 6, 2025, the Company received an amount of NIS 644,551 (approximately \$171,468), as an advance payment from the Israeli Innovation Authority (the "IIA") to fund the development of a device for the assessment of diabetic foot ulcers before skin breakage among diabetic patients. The IIA approved the Company's program with a budget in total amount NIS 4,603,938 (approximately \$1,222,786), which includes a grant of 40% or NIS 1,841,575 (approximately \$489,035). The IIA grant will be distributed in tranches based on specific milestones and the progress of the product development, from January 1, 2025 to December 31, 2025. In consideration of 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 SOFR rate. In addition, the IIA must approve any arrangement whereby the Subsidiary seeks to transfer the technology relating to the project, or its development, from Israel.

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, 2024, as filed with the Securities and Exchange Commission, or the SEC, on April 4, 2025. 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 in the process of developing point-of-care decision support devices based on the patented cutting-edge infrared spectroscopy and artificial intelligence, or AI, analysis technology platform, as a basis for point-of-care decision support devices. The electrooptic visual and infrared spectroscopy technology platform allows harmless and non-invasive gathering of bio-information from a patient's blood and tissue. Bioinformation is then analyzed using our AI-based algorithms to provide healthcare professionals with decision support in the assessment and monitoring of various disease conditions. We plan to use our proceeds to continue development efforts of our products, while mainly focusing on the DiaSafe™ device, production and marketing of PressureSafe™: commercial units, and working capital.

PressureSafe™: Our first product based on this platform, is a handheld device designed to revolutionize the early assessment of pressure injuries, or PIs, affecting the 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 assessment of PIs, regardless of patient skin tone, which we believe will drive equitable healthcare and help reduce the toll and cost of PIs. We plan to launch *PressureSafe™* as a decision support system, or DSS, tool for caregivers in hospitals, nursing homes, and home-care companies. On April 9, 2024, the *PressureSafe™* decision support device received U.S. Food and Drug Administration, or FDA, listing certification. *PressureSafe™* is classified as a Class I device. We are currently working on completing the development of the commercial version of the *PressureSafe™* device, with initial sales planned during the second half of 2025, following the listing by the FDA.

DiaSafe: Similarities in the physiological development of PIs and diabetic foot ulcers, or DFU, under the skin surface allow the IRMED *PressureSafe™* device to be adopted to support the early assessment of DFU among diabetic patients at high risk of developing DFU. We are assessing and planning the development of our second product, which is a handheld optical monitoring device that will support early assessment of DFUs in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole of diabetic patients, which sometimes is accompanied by other comorbidities as lower limb neuropathy.

Our novel technology platform will enable direct assessment of the development of a DFU before it becomes an open wound that may lead to limb amputation. The Israeli Innovation Authority, or IIA, has approved our plan to develop a diabetic foot ulcer device for early assessment of DFU. On January 25, 2024, the IIA approved a program to develop a device for the early assessment of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately US\$ 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, by 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 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. Following the IIA grant we plan to commence a clinical trial in the center of Israel's leading diabetes clinic. On July 15, 2024, we announced that we received a grant from the IIA in the amount of approximately \$500,000, to develop our platform technology for a new indication, a decision support device for the early assessment of diabetic foot ulcers. The grant's 13-month development was finalized, as we achieved the project's milestones. Computer simulations of infrared light reflectance from lesions under the skin surface have been completed.

Future indication as part of our research and development is an innovative otoscope, *Nobiotics*, to support physicians with an immediate indication as to whether middle 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 in large by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis remains a common occurrence.

Our initial focus is on the development of decision support system 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 skin-agnostic optical monitoring device that is being developed to support early assessment of PIs to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement; and
2. *DiaSafe*, a handheld optical monitoring device that is being developed to support early assessment of DFUs in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole of diabetic patients, which sometimes is accompanied by other comorbidities as lower limb neuropathy.

Recent Developments

Israeli Innovation Authority

On April 6, 2025, we received an amount of NIS 644,551 (approximately \$171,468), as an advance payment from the IIA to fund the development of a device for the assessment of diabetic foot ulcers before skin breakage among diabetic patients. The IIA approved a total budget in a total amount of NIS 4,603,938 (approximately \$1,222,786), which includes a grant of 40% or NIS 1,841,575 (approximately \$489,035). The IIA grant will be distributed in tranches based on specific milestones and the progress of product development, from January 1, 2025 to December 31, 2025. The approval of the research and development project by the IIA is subject to the provisions of the Encouragement of Industrial Research and Development Law, 5744-1984 (the “Innovation Law”), as well as the rules, procedures, and guidelines established by the IIA. Pursuant to the terms of the grant, we are required to comply with all applicable regulatory and reporting obligations, including limitations relating to intellectual property and changes in ownership or control. In addition, the Company is obligated to pay royalties to the IIA for revenues generated in connection with the approved project, in accordance with the terms set forth in the grant approval and the Innovation Law.

Director Appointment

On April 29, 2025, our board of directors (the “Board”) appointed Mr. Yechiel Even to serve as a Class I director to fill an existing vacancy on the Board, effective immediately. Mr. Even will serve until his earlier removal or resignation. The Board determined that Mr. Even is an independent director as defined under the Nasdaq Listing Rules and Rule 10A-3 under the Exchange Act of 1934. In addition, Mr. Even was appointed to serve on the Board’s audit committee. As remuneration for his service as a director, Mr. Even will receive the same fees as other non-executive directors. Except as otherwise set forth herein, there is no arrangement or understanding between us and Mr. Even and any other person pursuant to which he was elected as a director, and there are no transactions in which Mr. Even has an interest requiring disclosure under Item 404(a) of Regulation S-K. In connection with Mr. Even’s appointment, we expect to enter into our standard indemnification agreement with Mr. Even, on substantially the same terms as the indemnification agreements previously entered into between us and each of our directors and executive officers.

Results of Operations

Comparison of the Three Months Ended March 31, 2025, to the Three Months Ended March 31, 2024

	For the three months ended March 31,	
	2025	2024
	U.S dollars (in thousands)	
Research and development expenses, net	23	195
Marketing expenses	2	168
General and administrative expenses	228	295
Total operating expenses	253	658
Financial (income) expenses, net	520	(1)
Loss for the period	773	657

Revenues. During the three-month period ended March 31, 2025, and 2024, 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 \$195,000 during the three months ended March 31, 2024, to \$23,000 during the corresponding three-month period in 2025. The decrease 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 and the measures we implemented to cut our costs in response to our cash flow situation, a reduction in payroll expenses, and a reduction in 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 \$168,000 during the three months ended March 31, 2024, to \$2,000 during the corresponding three-month period in 2025. The decrease resulted primarily from the reduction in non-cash expenses attributable to stock-based compensation granted to employees and 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 \$295,000 during the three months ended March 31, 2024, to \$228,000 in the corresponding three-month period in 2025. The decrease in general and administrative expenses resulted primarily from a reduction in payroll expenses, and a reduction in fees for professional services following the cost-cutting measures we undertook as a response to our current cash flow limitations. partially offset by an increase in non-cash expenses recorded relating to stock-based compensation to an employee.

Loss. Loss for the three months ended March 31, 2024, was \$657,000 compared to \$773,000 for the corresponding three-month period in 2025. The increase in net loss is primarily attributable to the increase in non-cash expenses recorded relating to shares issued related to the equity purchase agreement, partially offset by a reduction in payroll expenses, and 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 and a reduction in fees for professional services following the cost-cutting measures we undertook as a response to our current cash flow limitations.

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 2022 and 2023, we raised aggregate gross proceeds of \$3,625,000 and \$1,000,000, respectively, from sales of our equity and equity linked securities. In addition, on June 4 and July 4, 2024, we received aggregate proceeds of \$755,000 from the sales of our shares of common stock and warrants to purchase shares of common stock in a private placement offering.

As of March 31, 2025, we had \$51,000 in cash resources and approximately \$617,000 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, 2025 (in thousands):

	For the three months ended	
	March 31, 2025	March 31, 2024
	US Dollars (In thousands)	
Net cash used in operating activities	(110)	(358)
Net cash provided from financing activities	31	-
		15

We have experienced operating losses since inception and had a total accumulated deficit of \$17,511,000 as of March 31, 2025. 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, 2025, and 2024, our cash used in operations was approximately \$110,000 and \$358,000, respectively. As we continue to conduct our business activities, we expect that the cash needed to fund our operations will increase significantly over the next several years, as we will need to continue and intensify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes, and pursue FDA clearance for our additional products, and international regulatory approvals.

On March 11, 2025, we entered into an Equity Purchase Agreement (the “Purchase Agreement”) with Williamsburg, pursuant to which Williamsburg agreed to purchase up to Fifteen Million Dollars (\$15,000,000) of our Common Stock (“Maximum Commitment Amount”) by delivering put notices (each, a “Put Notice”). The Purchase Agreement provides that we will sell the shares of Common Stock (the “Put Shares”) to Williamsburg pursuant to applicable Put Notices from time to time over a 24-month period (unless otherwise determined therein) in accordance with the terms and conditions the Purchase Agreement, commencing on March 11, 2025, and ending on the earlier of (i) the date on which the Williamsburg shall have purchased Put Shares pursuant to this Agreement equal to the Maximum Commitment Amount, (ii) March 11, 2027, or (iii) written notice of termination us to Williamsburg (which shall not occur at any time that Williamsburg holds any of the Put Shares) (the “Commitment Period”). Each Put Notice shall state the number of shares of the Common Stock Williamsburg is required to purchase, at such price as determined in accordance with the Purchase Agreement. The per share purchase price for the Put Shares shall be equal to 90% of the market price defined as the average of the two (2) lowest Volume-Weighted Average Price (“VWAP”) for the five (5) consecutive trading days immediately preceding the relevant clearing date, as reported by Bloomberg Finance L.P. or other reputable source. Pursuant to the Purchase Agreement, Williamsburg may not acquire at any point, more than 9.99% of our outstanding common stock. Pursuant to the terms of the Purchase Agreement, Williamsburg agreed to accept a Put Notice of up to \$500,000 upon a registration statement being declared effective by the SEC.

As stated in the Purchase Agreement, the “Principal Market” includes any of the national exchanges (i.e. NYSE, NYSE AMEX, NASDAQ), or principal quotation systems (i.e. OTCQX, OTCQB, OTC Pink, the OTC Bulletin Board), or other principal exchange or recognized quotation system which is at the time the principal trading platform or market for the Company’s Common Stock.

As consideration for its commitment to purchase Put Shares pursuant to the Purchase Agreement, the Company issued to Williamsburg 1,000,000 shares of Common Stock (the “Commitment Shares”) following the execution of the Purchase Agreement. The shares of Common Stock that may be issued to Williamsburg under the Purchase Agreement, including the Commitment Shares, were issued and will be issued pursuant to an exemption from registration under the Securities Act.

During the term of the Equity Purchase Agreement, we shall be entitled to put to the Investor, and the Investor shall be obligated to purchase, such number of shares of our common stock, such shares, the Put Shares, at such price as determined in accordance with the Equity Purchase Agreement. The per share purchase price for the Put Shares shall be equal to 90% of the market price defined as the average of the two (2) lowest Volume-Weighted Average Price (VWAP) for the five (5) consecutive trading days immediately preceding the relevant Clearing Date (defined therein), as reported by Bloomberg Finance L.P. or other reputable source. Further, in consideration of our Put rights, and subject to the terms of the Equity Purchase Agreement, we will issue to the Investor 1,000,000 shares of our common stock. Pursuant to the Equity Purchase Agreement, the Investor may not acquire at any point, more than 9.99% of our outstanding common stock.

Effective March 26, 2025, we entered into a Note Purchase Agreement, or the Purchase Agreement, with Mr. Ran Ziskind, Mr. Yaniv Cohen, and Mr. Oded Bashan for an aggregate amount of \$31,200. Pursuant to the Purchase Agreement, we issued unsecured convertible promissory notes, or the Notes, to Mr. Ziskind, Mr. Cohen, and Mr. Bashan in the principal amount of \$10,400 for each Note. The Notes bear simple interest at a rate of 9% per annum and mature on the earlier of (i) March 26, 2026, or (ii) upon the completion by us of an equity or debt financing generating gross proceeds of at least \$100,000. The Notes are convertible, at the election of the holder, on the maturity date into our shares of common stock at a price per share equal to 85% of the closing price of the common stock on the applicable trading market as of the maturity date. The Notes are subject to customary events of default, upon which the outstanding principal and accrued interest may become immediately due and payable. We may not prepay the principal amount without the consent of a majority of the holders of all outstanding Notes, though accrued interest may be paid at any time.

We will 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 second quarter of 2025. 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 *DiaSafe*™ 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, 2025, 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

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of March 31, 2025, 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, 2025, 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 ended March 31, 2025, 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

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

On November 27, 2024, the first pre-trial hearing in the case was held. After directing questions for clarification to the parties, the honorable court referred the parties to mediation. Mediation sessions were held in January 2025, and April 2025. The parties informed the honorable court on April 23, 2025, of the failure of the mediation process.

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

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the factors discussed in Part I, "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024, which could materially affect our business, financial condition, or future results.

There have been no material changes from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024, except as noted below.

Significant changes or developments in U.S. laws or policies, including changes in U.S. trade policies and tariffs and the reaction of other countries thereto, may have a material adverse effect on our business and financial statements.

Significant changes or developments in U.S. laws and policies, such as laws and policies surrounding international trade, foreign affairs, manufacturing and development and investment in the territories and countries where we or our customers operate, can materially adversely affect our business and financial statements. Tariffs imposed by the U.S. government, may increase the cost of certain raw materials and components used in our products. If these tariffs remain in place or are expanded, or if new trade restrictions are implemented, our manufacturing costs could increase, which could materially and adversely affect our margins and financial results.

Furthermore, changes in trade policy have increased uncertainty in our industry, and any escalation in trade tensions could disrupt our supply chain, delay production timelines, or require costly modifications to sourcing and logistics strategies. The extent and duration of the tariffs and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the U.S. and affected countries, the responses of other countries or regions, exemptions or exclusions that may be granted, availability and cost of alternative sources of supply, and demand for our products in affected markets.

ITEM 5. OTHER INFORMATION

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*	<u>Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934</u>
31.2*	<u>Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934</u>
32.1**	<u>Certification of Chief Executive Officer (Principal Executive Officer), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	<u>Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934</u>
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/ Ran Ziskind
Ran Ziskind
Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2025

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

Date: May 15, 2025

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

I, Ran Ziskind, 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/ Ran Ziskind
Ran Ziskind, Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2025

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, 2025

**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, 2025 (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/ Ran Ziskind

Ran Ziskind, Chief Executive Officer
(Principal Executive Officer)

Dated: May 15, 2025

**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, 2025 (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, 2025
