

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

FORM 10-Q

MARK ONE

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

For the Quarterly Period ended September 30, 2024

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

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

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

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

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

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

Large accelerated filer	<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 November 14, 2024, there were outstanding 71,008,144 shares of the registrant's common stock, par value \$0.001 per share.

IR-MED, INC.
Form 10-Q
September 30, 2024

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Interim Unaudited Condensed Consolidated Balance Sheets

	Note	September 30 2024	December 31 2023
		U.S dollars (in thousands)	
Assets			
Current assets			
Cash and cash equivalents		392	767
Accounts receivable		51	81
Total current assets		443	848
Non- current assets			
Long term restricted deposit		11	11
Operating right of use asset		40	84
Property and equipment, net		39	56
Total non-current assets		90	151
Total assets		533	999
Liabilities and Stockholders' equity			
Current liabilities			
Trade and other payables	5	376	473
Non-current liabilities			
Stockholders' loans		155	161
Total liabilities		531	634
Contingent liabilities and commitments	7		
Stockholders' Equity			
Common Stock, par value \$0.001 per share, 600,000,000 and 250,000,000 shares authorized as of September 30, 2024, and December 31, 2023, respectively. 70,783,144 and 69,931,056 shares issued as of September 30, 2024, and December 31, 2023, respectively.			
		70	69
Additional paid-in capital		16,392	15,135
Accumulated deficit		(16,460)	(14,839)
Total Stockholders' equity		2	365
Total liabilities and stockholders' equity		533	999

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

Interim Unaudited Condensed Consolidated Statements of Operations

	For the three-months period ended September 30		For the nine-months period ended September 30	
	2024	2023	2024	2023
	U.S dollars (in thousands)			
Research and development expenses				
Expenses incurred	257	469	881	1,570
Less- government grants	(52)	-	(387)	-
Research and development expenses, net	205	469	494	1,570
Marketing expenses	29	297	225	631
General and administrative expenses	367	431	898	1,448
Total operating loss	601	1,197	1,617	3,649
Financial expenses (income), net	(3)	(18)	4	(11)
Loss for the period	598	1,179	1,621	3,638
Basic and dilutive loss per common stock (in U.S. dollars)	(0.01)	(0.02)	(0.02)	(0.05)
Weighted average number of ordinary shares	70,758,796	68,836,598	70,305,346	69,233,573

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

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	<u>Common Stock</u>		<u>Additional paid-in Capital</u>	<u>Accumulated deficit</u>	<u>Total Stockholders' equity</u>
	<u>Number of Shares</u>	<u>Amount</u>			
U.S dollars (in thousands)					
For the nine-months period ended September 30, 2024					
Balance as of January 1, 2024	69,931,056	69	15,135	(14,839)	365
Private placement of common stock and warrants	755,000	1	754	-	755
Stock-based compensation	97,088	-	503	-	503
Loss for the period	-	-	-	(1,621)	(1,621)
Balance as of September 30, 2024	<u>70,783,144</u>	<u>70</u>	<u>16,392</u>	<u>(16,460)</u>	<u>2</u>
	<u>Common Stock</u>		<u>Additional paid-in Capital</u>	<u>Accumulated deficit</u>	<u>Total Stockholders' equity</u>
	<u>Number of Shares</u>	<u>Amount</u>			
U.S dollars (in thousands)					
For the nine-months period ended September 30, 2023					
Balance as of January 1, 2023	68,808,970	68	12,454	(9,930)	2,592
Private placement of common stock and warrants, net	1,000,000	1	999	-	1,000
Stock-based compensation	64,454	-	1,258	-	1,258
Loss for the period	-	-	-	(3,638)	(3,638)
Balance as of September 30, 2023	<u>69,873,424</u>	<u>69</u>	<u>14,711</u>	<u>(13,568)</u>	<u>1,212</u>

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

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
U.S dollars (in thousands)					
For the three-month period ended September 30, 2024					
Balance as of July 1, 2024	70,699,144	70	16,155	(15,862)	363
Private placement of common stock and warrants	40,000	*	40	-	40
Stock-based compensation	44,000	-	197	-	197
Loss for the period	-	-	-	(598)	(598)
Balance as of September 30, 2024	70,783,144	70	16,392	(16,460)	2

(*)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-months period ended September 30, 2023					
Balance as of July 1, 2023	69,829,424	69	14,328	(12,389)	2,008
Stock-based compensation	44,000	-	383	-	383
Loss for the period	-	-	-	(1,179)	(1,179)
Balance as of September 30, 2023	69,873,424	69	14,711	(13,568)	1,212

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

Interim Unaudited Condensed Consolidated Statements of Cash Flows

	For the nine-months period ended	
	September 30	September 30
	2024	2023
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	(1,621)	(3,638)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	503	1,258
Depreciation	17	17
Accrued financial expenses (income), net	4	(11)
Decrease (increase) in accounts receivable	30	(28)
Decrease in trade and other payables	(58)	(76)
Net cash used in operating activities	(1,125)	(2,478)
Cash flows from investing activities		
Purchase of property and equipment	-	(1)
Net cash used in investing activities	-	(1)
Cash flows from financing activities		
Proceeds from private placement of common stock and warrants, (see also Note 4.3, and Note 4.4)	755	1,000
Repayment of shareholder loan	(5)	-
Net cash provided by financing activities	750	1,000
Effect of exchange rate changes on cash and cash equivalents	-	1
Net decrease in cash and cash equivalents	(375)	(1478)
Cash and cash equivalents as at the beginning of the period	767	3,002
Cash and cash equivalents as at the end of the period	392	1,524

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

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 1 - General**A. Description of Business**

IR-Med, Inc. (OTC QB: IRME, hereinafter: the “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. (the “Subsidiary”) are located in Rosh Pina, Israel. The Parent Company and the Subsidiary are at times collectively referred to as the “Company”.

On April 9, 2024, the Company’s first device, the *PressureSafe*, decision support device received a U.S. Food and Drug Administration (FDA) listing certification. *PressureSafe* is classified as a Class I device. Following the listing certification of the *PressureSafe* device, the Company has started the preparations for the commercial launch of its first device, the *PressureSafe*. The Company is developing its technology through its Subsidiary and is utilizing Infra-Red-light spectroscopy (IR) combined with an Artificial Intelligence (AI) technology platform to develop non-invasive devices for various medical indications, by detecting and measuring various biomarkers and molecules in the blood and in human tissue in real-time. The initial product candidates which are currently in various stages of development are non-invasive, user friendly and designed to address the medical needs of large and growing target patient groups by offering earlier and more accurate information for detection, which is expected to reduce healthcare expenses and reduce the widespread reliance on antibiotics administration, and other interventional options optimizing the delivery of targeted medical services.

B. Going Concern

The Company is starting preparations for the commercial launch of its first device the “PressureSafe” 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 candidates and initiate market activities for its first commercial product. During the nine months ended September 30, 2024, the Company has incurred losses of \$1,621 thousand and had a negative cash flow from operating activities of \$1,125 thousand. The accumulated deficit as of September 30, 2024 is \$16,460 thousand.

Based on the current expected level of operating expenditures, the Company’s cash resources as of September 30, 2024 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 of its 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 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 significant 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

Further to the described in Note 1B to the Company’s Annual Report on for the year ended December 31, 2023, 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.

The Company assesses, on the basis of the information it has as of the date of the approval of these financial statements, that the current events and the escalation in security in Israel, may have a material effect on its business plans in the short term and may cause delays in the Company’s research and development activities and in its marketing efforts. Since this is an event that is not under the control of the Company and matters such as the continuation of the multi front war in Israel may affect the Company’s assessments, as of the reporting date the Company is unable to assess the extent of the effect of the Iron Swords War on its business.

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, 2023.

In the opinion of management, all adjustments considered necessary for a fair statement, consisting of normal recurring adjustments, have been included. Operating results for the three and nine months period ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024.

Use of Estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions including fair value of 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, 2023.

Accounting Standards Updates Issued, but Not Adopted

Income Taxes: In December 2023, the Financial Accounting Standards Board (“FASB”) issued an Accounting Standards Update (“ASU”) 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments in this ASU add specific requirements for income tax disclosures to improve transparency and decision usefulness. The guidance in ASU 2023-09 requires that public business entities disclose specific categories in the income tax rate reconciliation and provide additional qualitative information for reconciling items that meet a quantitative threshold. In addition, the amendments in ASU 2023-09 require that all entities disclose the amount of income taxes paid disaggregated by federal, state, and foreign taxes and disaggregated by individual jurisdictions. The ASU also includes other disclosure amendments related to the disaggregation of income tax expense between federal, state and foreign taxes. For public business entities, the amendments in this update are effective for annual periods beginning after December 15, 2024. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The amendments in this update should be applied on a prospective basis and retrospective application is permitted. The Company is currently evaluating this ASU to determine its impact on the Company’s disclosures.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 3 - Significant Accounting Policies (cont'd)

Segment Reporting: In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures*. These amendments require, among other things, that a public entity that has a single reportable segment provide all the disclosures required by the amendments in this ASU and all existing segment disclosures in Topic 208. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. A public entity should apply the amendments retrospectively to all periods presented in the financial statements. The Company is currently evaluating this ASU to determine its impact on the Company's disclosures.

Income—Expense Disaggregation Disclosures: In November 2024, the FASB issued ASU No. 2024-03 *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures* (Subtopic 220-40). The ASU improves the disclosures about a public business entity's expenses and provides more detailed information about the types of expenses in commonly presented expense captions. The amendments require that at each interim and annual reporting period an entity will, inter alia, disclose amounts of purchases of inventory, employee compensation, depreciation and amortization included in each relevant expense caption (such as cost of sales, SG&A and research and development). Amounts remaining in relevant expense captions that are not separately disclosed will be described qualitatively. Certain amounts that are already required to be disclosed under currently effective GAAP will be included in the same disclosure as the other disaggregation requirements. The amendments also require disclosing the total amount of selling expenses and, in annual reporting periods, the definition of selling expenses. The ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating this ASU to determine its impact on the Company's disclosures.

Note 4 – Significant Events During the Reporting Period

- On January 25, 2024, the Israel Innovation Authority (the "IIA") approved the Company's proposed program to develop a device for the early detection of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately \$1,030,000), which includes an amount equal to 50% grant of the total budget provided at the time of the grant, disbursed in installments over the course of 13 months, in accordance with the project's progress. In consideration for the grant by the IIA, the subsidiary is required to pay royalties at the rate of 3%-5% from the total sales until the repayment date of the full amount of the grant, plus annual interest at the Secured Overnight Financing Rate (SOFR) rate. In addition, the IIA must approve any arrangement whereby the Company seeks to transfer the technology relating to the project, or its development, from Israel.
- In 2015, certain of the Company's stockholders granted loans to the Company to finance its ongoing operation (hereinafter: the "2015 Loans"). These loans bear interest at an annual rate ranging in 2023 and 2022 from 2.90% to 2.42%. Under the original loan terms, the aggregate loan amount is payable to the lenders by the Company only upon the approval of the Company's board of directors that the Company's profits reached an amount of US\$500 thousand and upon such terms and in such installments as shall be determined by the Company's board of directors.

In March 2020, the Company and the lender agreed to amend the terms of the 2015 Loan and the repayment date was extended to December 31, 2023. On March 1, 2024, the Company and the lender agreed to extend the repayment date to December 31, 2025.

In 2017, one of the Company's shareholders provided the Company with a loan to finance its ongoing operation (hereinafter: the "2017 Loan"). This loan bears interest at annual rate ranging in 2023 and 2022 from 2.90% to 2.42% annually. Under the original loan terms, the aggregate loan amount was repayable by the Company upon the closing of an investment in the Company with proceeds greater than US\$500 thousand.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 4 – Significant Events During the Reporting Period (cont'd)

In March 2020, the Company and the lender agreed to amend the terms of the 2017 Loan and the repayment date was extended to December 31, 2023. On March 1, 2024, the Company and the lender agreed to extend the repayment date to December 31, 2025.

On March 6, 2018, certain of the Company's shareholders entered with the Company into a convertible bridge loan agreement (the "2018 CLA").

In accordance with 2018 CLA, the loan bears interest at a rate per annum equal to three percent (3%) compounded and accrued annually, and was originally repayable on December 31, 2018, or later date as determined by the shareholders representing more than 80% of the Subsidiary issued and outstanding shares who has also provided loans with terms similar to the terms of the agreement ("Majority Lenders"), unless earlier converted to shares.

The CLA included certain scenarios in which the loan may be converted ("Optional conversion"), and certain scenarios in which the loan is automatically converted.

In case of an exit event, as described in the 2018 CLA, the loan and all accrued interest will be either converted to shares or repaid at 200% of the outstanding amount all as per the Majority lenders decision.

The Company recorded the loan amount as a liability, applying the accounting guidance in Accounting Standard Codification 835-30. The embedded derivatives identified by the Company relating to the Exit event and Optional conversion were estimated by the Company as immaterial amounts.

In late 2018, the Majority Lenders agreed to defer the repayment date of the loan to a later date, after December 31, 2019. During 2018 and 2019 the convertible loan was not converted into shares.

In March 2020, the Company and the lenders agreed to amend and restate the 2018 CLA ("the Amended CLA") pursuant to which the lenders waived any and all rights to convert their respective outstanding loan amounts, and the repayment date was set to December 31, 2023. In addition, in case of an Exit event, as described in the Amended CLA, the loan and all accrued interest will be fully repaid immediately following the exit event.

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

On July 3, 2024, the board of directors approved a one-time repayment of NIS 18,750 under the loan agreement to Mr. Klein.

Due to these agreements between the stockholders and the Company regarding the repayment date of the loans, the stockholders' loans are classified as non-current liabilities.

3. On June 4, 2024, the Company, entered into a securities purchase agreement with certain, pursuant to which the Company agreed to issue and sell, in a private placement offering, 715,000 shares of the Company's common stock, at a per share price of \$1.00 and warrants to purchase up to an additional 1,144,000 shares of common stock. The warrants are exercisable beginning on the six (6) month anniversary of their issuance, have a term of five years from the initial exercise date and entitle the holders to purchase up to 1,144,000 shares of common stock. The warrants have an exercise price of \$1.00 per share and contain a one-time dilution protection in the event the Company sells securities at a price less than the then exercise price in effect in a public offering in conjunction with a listing on a national securities exchange. The offering closed on June 7, 2024 and the Company received aggregate gross proceeds of \$715,000.
4. On July 4, 2024, the Company entered into securities purchase agreements with a certain investor, pursuant to which it agreed to issue and sell, in a private placement offering, 40,000 shares of its common stock, at a per share price of \$1.00 and warrants to purchase up to an additional 64,000 shares of common stock. The offering closed on July 10, 2024, and the Company received aggregate gross proceeds of \$40,000. This transaction was part of the securities purchase agreements that were closed on June 7, 2024 (see section 3 above).

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 4 – Significant Events During the Reporting Period (cont'd)

- On July 7, 2024, the Company entered into an Amendment to the Consulting Agreement with Mr. Aharon Klein, its Interim Chief Executive Officer and Chief Technology Officer and (the “Klein Amendment”). The Klein Amendment amends the original consulting agreement executed by and between the Company and Mr. Klein, dated October 1, 2019, as amended on December 24, 2020. Effective June 1, 2024, the Klein Amendment provides for a monthly compensation in the amount of NIS 30,000 and an additional NIS 5,000 for car expenses. All other terms related to Mr. Klein overall compensation and equity-based awards remain unchanged. On October 31, 2024, the Board approved a reduction in the monthly payments made to Mr. Klein, in light of the Company’s current cash position, which was agreed upon with Mr. Klein. Under the amended terms of Mr. Klein’s service provider agreement, he will receive monthly payments of NIS 16,000, instead of NIS 30,000, plus NIS 5,000 for car expenses totaling a monthly compensation of NIS 21,000 starting from October 2024 onwards.
- On July 7, 2024, the Company entered into an Amendment to the Consulting Agreement with Dr. Yaniv Cohen, Chief Scientific Officer of the Company (the “Cohen Amendment”). The Cohen Amendment amends the original consulting agreement executed by and between the Company and Dr. Cohen, dated November 1, 2019, and provides for monthly consideration of NIS 15,000, commencing as of June 1, 2024. On October 31, 2024, the Board of Directors approved the reduction in the monthly payments made to Dr. Cohen, pursuant to his service provider agreement, from his current rate of NIS 15,000 to NIS 8,000, commencing in October 2024.
- On August 21, 2024, the Board appointed Mr. Ran Ziskind to serve as the Company’s Chief Executive Officer (CEO), replacing Mr. Ronnie Klein, who had been serving as Interim CEO, effective September 1, 2024. Mr. Ziskind also serves as the Chief Executive Officer of the Company’s wholly-owned subsidiary, IR-Med Ltd., an Israeli corporation. In conjunction with his appointment, the Company entered into an employment agreement with Mr. Ziskind (the “Employment Agreement”), pursuant to which he will be subject to standard confidentiality, intellectual property assignment and non-compete provisions. In addition, in consideration for his service, Mr. Ziskind receives a monthly gross salary of NIS 6,000 until the Company will raise at least \$4,000,000 in funding, and following such potential capital raise, his compensation will be increased to NIS 45,000 per month, as well as will be entitled to NIS 10,000 for car expenses. Under the Employment Agreement, Mr. Ziskind will also receive 1,400,000 restricted shares of the Company’s Common Stock, at an exercise price of \$0.58 per share (the “Shares”). The Shares will vest over a four-year period commencing on the grant date such that (i) 350,000 of the Shares will become fully vested and exercisable on the first anniversary elapsed from the grant date and (ii) the balance will vest in six (6) bi-annual installments of 175,000 Shares, subject to Mr. Ziskind’s continued employment.

Note 5 - Trade and Other Payables

	September 30 2024	December 31 2023
	US Dollars (In thousands)	
Trade payables	35	62
Accrued expenses	157	160
Payroll and related	66	98
Advance from customer	50	50
Lease liability	-	39
Related Parties	68	64
	<u>376</u>	<u>473</u>

Note 6 - 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 Company to officers, directors, employees and consultants.

As of September 30, 2024, the Company awarded to its employees and service providers options to purchase up to 15,428,175 shares of Common Stock, of which options for 7,567,675 shares were at an exercise price of \$0.32 per share, options for 7,305,000 shares were at an exercise price of \$0.58 per share, options for 555,500 shares were at an exercise price of \$0.01 per share. As of September 30, 2024, options for 13,139,791 shares were vested with a weighted average of exercise of \$0.41 and the remaining balance has a vesting period ranging between one months to four years. The options are exercisable for periods ranging between three to ten years from the vesting date.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 6 - Stock options plan (Cont'd)

	Weighted average of exercise price	Number of options
Outstanding as of beginning of year	\$ 0.42	15,544,175
Forfeited	\$ 0.48	(1,831,500)
Granted	\$ 0.55	1,715,500
Outstanding as of September 30, 2024	\$ 0.43	15,428,175

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.

In addition, during the nine months ended September 30, 2024, the Company issued to service providers and consultants 97,088 shares of the Company's common stock for no consideration.

The Company recorded in the statement of operations a non-cash expense of \$503 thousand and \$1,258 thousand during the nine months ended September 30, 2024 and 2023, respectively.

The stock-based compensation expenses for the three and nine months ended September 30, 2024 and 2023 were recognized in the statements of operations as follows:

	For the three-month period ended		For the nine-month period ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
US Dollars (In thousands)				
Research and development expenses	16	36	56	119
Marketing expenses	28	173	219	486
General and administrative expenses	153	174	228	653
	197	383	503	1,258

The following table sets forth information about the weighted-average fair value of options granted to employees and service providers during the nine months period ended September 30, 2024 and 2023, using the Black-Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

	For the nine-month period ended	
	September 30, 2024	September 30, 2023
Dividend yields (see (I) below)	0.0	0.0%
Share price (in U.S. dollar) (see (II) below)	0.53-0.64	0.53-0.64
Expected volatility (see (III) below)	116. % - 84%	116. % - 95.37%
Risk-free interest rates (see (IV) below)	3.61% - 4.39%	3.61% - 4.16%
Expected life (in years) (see (V) below)	1.5 - 14.79	1.5 - 14.79

- I. The Group used 0% as its expected dividend yield, based on historic policies and future plans.
- II. The Company's common stock is quoted on the OTCQB. However, the Company considers its share price as it is traded on OTCQB to not be an appropriate representation of fair value, since it is not traded on an active market. The Company determined that the market is inactive due to low level of activity of the Company's common stock, stale or non-current price quotes and price quotes that vary substantially either over time or among market makers. Consequently, the price of the Company's common stock has been determined based on private placement equity offerings conducted in April 2021, July 2022 and June 2023 consisting of units comprised of shares of common stock and warrants, at a per unit purchase price of \$0.64, \$0.88 and \$1.00, respectively. In order to evaluate the price per share, the warrant value has been deducted from the total unit price.
- III. As the Company is at its early stage of operation, there is not sufficient historical volatility for the expected term of the stock options. Therefore, the 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.

Note 7 - 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 (the "Plaintiff") who provided, on a 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.

The Company records a provision in its financial statements to the extent that it concludes that a contingent liability is probable, and the amount thereof is reasonably estimable. The Company's management assesses that the likelihood of the lawsuit succeeding is low. However given the preliminary stage of the proceedings, the

extent and amount of potential damages arising from the lawsuit cannot be determined at this time, therefore no provisions have been made regarding the matter disclosed in this note.

Accordingly, management's assessments involve complex judgments about future events and often rely heavily on estimates and assumptions.

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

Forward-looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws, and is subject to the safe-harbor created by such Act and laws. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "potential" or "continue," the negative of such terms, or other variations thereon or comparable terminology. The statements herein and their implications are merely predictions and therefore inherently subject to known and unknown risks, uncertainties, assumptions and other factors that may cause actual results, performance levels of activity, or our achievements, or industry results to be materially different from those contemplated by the forward-looking statements. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading "Risk Factors" in Part I, Item 1A, of our Annual Report on Form 10-K/A for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission, or the SEC, on April 8, 2024. As used in this quarterly report, the terms "we", "us", "our", the "Company" and "IR-Med" mean IR-Med, Inc. and our wholly-owned subsidiary IR. Med Ltd. unless otherwise indicated or as otherwise required by the context.

Overview

We were incorporated in the State of Nevada in April 2007 under the name "Monster Motors, Inc." We began operating the business of IR. Med Ltd., an Israeli company, through a reverse acquisition on December 24, 2020. IR. Med Ltd. (an Israeli company which was founded in 2013) continues to operate as our operating subsidiary, and we are the sole stockholder of IR. Med Ltd. Our corporate headquarters and research facilities are located at ZHR Industrial Zone, Rosh Pina, Israel.

We are in the process of developing point-of-care decision support devices based on the patented cutting-edge infrared spectroscopy and artificial intelligence (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 detection and monitoring of various disease conditions.

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

DiaSafe: Similarities in the physiological development of PIs and diabetic foot ulcers ("DFU") under the skin surface allow the IRMED *PressureSafe* device to be adopted to support the early detection 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 detection of DFUs in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole among diabetic patients a condition, 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 (the "IIA") has approved our plan to develop a diabetic foot ulcer device for early detection of DFU. On January 25, 2024, the IIA approved a program to develop a device for the early detection of diabetic foot ulcers among diabetic patients, with a project budget of NIS 3,761,978 (approximately 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. As of September 30, 2024 we received a grant from the IIA in the amount of approximately \$387,000, to develop our platform technology for a new indication, a decision support device for the early detection of diabetic foot ulcers. The grant's 13-month development timeline is proceeding on schedule, as we have achieved the mid-point milestones. Computer simulations of infrared light reflectance from lesions under the skin surface have been completed, and based on these data, we are building the DiaSafe™ device's hardware in accordance with the development plan agreed upon with the IIA.

Future indication as part of our research and development is an innovative otoscope, *Nobiotics*, to support physicians with an immediate indication as to whether mid-ear infection (otitis media), a common malady in children, is of a bacterial origin and thus requiring antibiotic treatment, or of a viral origin that consequently does not require antibiotic treatment.

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

The global diagnostics market is driven 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 detection 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 detection of DFUs in lower limb skin and underlying tissue, primarily caused by prolonged pressure on the sole of the foot, among diabetic patients a condition, which sometimes is accompanied by other comorbidities as lower limb neuropathy.

On April 9, 2024, the *PressureSafe* decision support device received an FDA listing certification. *PressureSafe* is classified as a Class I device and is exempt from 510(k) premarket submission. We are currently working on completing larger scale production of the commercial version of the *PressureSafe* device, with initial sales planned during the first half of 2025, following the listing with the FDA.

Recent Developments

On August 21, 2024, our board of directors (the "Board") appointed Mr. Ran Ziskind to serve as our Chief Executive Officer (CEO), replacing Mr. Ronnie Klein, who had been serving as Interim CEO, effective September 1, 2024. Mr. Ziskind also serves as the Chief Executive Officer of our wholly-owned subsidiary, IR-Med Ltd., an Israeli corporation. In conjunction with his appointment, we entered into an employment agreement with Mr. Ziskind (the "Employment Agreement"), pursuant to which he will be subject to standard confidentiality, intellectual property assignment and non-compete provisions. In addition, in consideration for his service, Mr. Ziskind receives a monthly gross salary of NIS 6,000 until we will raise at least \$4,000,000 in funding, and following such potential capital raise, his compensation will be increased to NIS 45,000 per month, as well as will be entitled to NIS 10,000 for car expenses. Under the Employment Agreement, Mr. Ziskind will also receive 1,400,000 restricted shares of our Common Stock, at an exercise price of \$0.58 per share (the "Shares"). The Shares will vest over a four-year period commencing on the grant date such that (i) 350,000 of the Shares will become fully vested and exercisable on the first anniversary elapsed from the grant date and (ii) the balance will vest in six (6) bi-annual installments of 175,000 Shares, subject to Mr. Ziskind's continued employment.

On September 10, 2024, we announced the start of a usability study for our lead product, PressureSafe™, at San Antonio, Texas based Methodist Healthcare. The study, titled “Safety and Efficacy of the PressureSafe Device for Early Detection of Pressure Injury in People with Various Skin Tones, Including Dark Skin Tones,” has received approval from Methodist Healthcare and has commenced patient enrollment and monitoring. Methodist Healthcare is widely regarded as one of the most respected healthcare providers in its region. With a growing network of care locations including hospitals, surgery centers, ERs, and family health clinics, each year Methodist Healthcare serves 608,000 patients, including 11,000 births, and 330,000 ER visits. The study aims to improve the early detection and prevention of pressure injuries among all patients. Importantly, the study aims to address the substantial challenge of healthcare inequality in the detection of pressure injuries in people of dark skin tones who are more than twice as likely to suffer from pressure injuries than those with lighter skin tone, according to a 5-year study published in Wounds. The current standard of care relies on visual inspection of the skin, which can be less effective for early detection in individuals with darker skin tones. Up to 104 people will be enrolled in the study, approximately half with dark skin tones. Registered nurses specialized in wound care (WOCN) will be trained in using PressureSafe™. Sensitivity and specificity will be assessed and compared to standard of care visual skin assessment done by the WOCN nurses.

On October 15, 2024, we announced the termination of our Distribution and License Agreement with PI Prevention Care LLC, or the Distributor, dated October 7, 2022, as a result of our notice to the Distributor of the Distributor’s material breach of the Distribution and License following its failure to timely pay the license fee as required.

On October 31, 2024, our Board approved a reduction in the monthly payments made to Mr. Aharon Klein, our Chief Technology Officer, in light of our current cash position, which was agreed upon with Mr. Klein. Under the amended terms of Mr. Klein’s service provider agreement, he will receive monthly payments of NIS 16,000, instead of NIS, 30,000, plus NIS 5,000 for car expenses totaling a monthly compensation of NIS 21,000 starting from October 2024 onwards.

On October 31, 2024, the Board of Directors approved the reduction in the monthly payments made to Mr. Yaniv Cohen, our Chief Scientific Officer, pursuant to his service provider agreement, from his current rate of NIS 15,000 to NIS 8,000, commencing in October 2024.

Key Financial Terms and Metrics

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

Revenues

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

Research and Development Expenses

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

Our research and development costs are comprised of:

- internal recurring costs, such as personnel-related costs (salaries, employee benefits, equity compensation, and other costs), materials and supplies, facilities and maintenance costs attributable to research and development functions; and
- fees paid to external parties who provide us with contract services, such as preclinical testing, manufacturing, related testing, and clinical trial activities.
- Less grants received from government authorities

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 fees and interest on stockholders' loans.

Results of Operations

Comparison of the nine months ended September 30, 2024 to the nine months ended September 30, 2023

Revenues. During the nine-month period ended September 30, 2024 and 2023, we did not record any revenues from operations.

Research and Development Expenses, Net. Research and development expenses consist of salaries and related expenses, consulting fees, service provider costs, and overhead expenses less grants received. Research and development expenses decreased from \$1,570,000 during the nine months ended September 30, 2023, to \$494,000 during the corresponding nine-month period in 2024. 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, a reduction in payroll expenses, proceeds of a grant from the IIA, 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 \$631,000 during the nine months ended September 30, 2023 to \$225,000 during the corresponding nine-month period in 2024. The decrease in marketing expenses resulted primarily from the reduction in professional services, and a reduction in non-cash expenses attributable to stock-based compensation 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 \$1,448,000 during the nine months ended September 30, 2023 to \$898,000 in the corresponding nine months period in 2024. The decrease in general and administrative expenses resulted primarily from a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers, a reduction in payroll expenses, and a reduction in fees for professional services.

Loss. Loss for the nine months ended September 30, 2023 was \$3,638,000 compared to \$1,621,000 for the corresponding nine month period in 2024. The decrease in net loss is primarily attributable to a decrease in use of third-party contractors for further research and development activities due to the completion of the development of the *PressureSafe* device, proceeds of a grant from the IIA, a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers and a reduction in payroll expenses and a reduction in fees for professional services.

	For the nine months ended	
	September 30,	
	2024	2023
	U.S. dollars (in thousands)	
Research and development expenses, net.	494	1,570
Marketing expenses	225	631
General and administrative expenses	898	1,448
Total operating expenses	1,617	3,649
Financial expenses (income), net	4	(11)
Loss for the period	1,621	3,638

Comparison of the three months ended September 30, 2024 to the three months ended September 30, 2023

Revenues. During the three-month period ended September 30, 2024 and 2023, we did not record any revenues from operation.

Research and Development Expenses. Research and development expenses consist of salaries and related expenses, consulting fees, service provider costs, and overhead expenses less grants received. Research and development expenses decreased from \$469,000 during the three months ended September 30, 2023 to \$205,000 during the corresponding three month period in 2024. 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, a reduction in payroll expenses, proceeds of a grant from the IIA, 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 \$297,000 during the three months ended September 30, 2023 to \$29,000 during the corresponding three month period in 2024. The decrease in marketing expenses resulted primarily from the reduction in professional services, and a reduction in non-cash expenses attributable to stock-based compensation 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 \$431,000 during the three months ended September 30, 2023 to \$367,000 in the corresponding three month period in 2024. The decrease in general and administrative expenses resulted primarily from a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers, and service providers, a reduction in payroll expenses, and a reduction in fees for professional services.

Loss. Loss for the three months ended September 30, 2023 was \$1,179,000 compared to \$598,000 for the corresponding three month period in 2024. The decrease in net loss is primarily attributable to non-cash expenses due to a decrease in use of third-party contractors for further research and development activities due to the completion of the development of the *PressureSafe* device, proceeds of a grant from the IIA, a decrease in non-cash expenses attributable to stock-based compensation to our directors, officers and service providers and a reduction in payroll expenses and a reduction in fees for professional services.

	For the three months ended	
	September 30,	
	2024	2023
	U.S. dollars (in thousands)	
Research and development expenses, net	205	469
Marketing expenses	29	297
General and administrative expenses	367	431
Total operating expenses	601	1,197
Financial income, net	(3)	(18)
Loss for the period	598	1,179

Financial Condition, Liquidity and Capital Resources

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

From inception, we have funded our operations from a combination of loans and sales of equity instruments. In 2021 and 2022, we raised aggregate gross proceeds of \$5,830,000 and \$3,625,000, respectively, from sales of our equity and equity linked securities. In addition, on June 12, 2023, we raised aggregate gross proceeds of \$1,000,000 from sales of our shares of common stock and warrants to purchase shares of common stock. On June 4, 2024, and July 10, 2024, we raised aggregate gross proceeds of \$755,000 from sales of our shares of common stock and warrants to purchase shares of common stock.

As of September 30, 2024, we had \$392,000 in cash resources and approximately \$531,000 of liabilities, including \$376,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the nine months ended September 30, 2024 (in thousands):

	For the nine months ended	
	September 30, 2024	September 30, 2023
	U.S. Dollars (In thousands)	
Net cash used in operating activities	(1,125)	(2,478)
Net cash used in investing activities	-	(1)
Net cash provided by financing activities	750	1,000

We have experienced operating losses since inception and had a total accumulated deficit of \$16,460,000 as of September 30, 2024. We expect to incur additional costs and will require additional capital to realize our business plans. These losses have resulted from significant cash expenditures used in operations. During the nine months ended September 30, 2024 and 2023, our cash used in operations was approximately \$1,125,000 and \$2,478,000, respectively. As we continue to conduct our business activities, we expect that the cash needed to fund our operations will increase significantly over the next several years, as we will need to continue and intensify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes, and pursue FDA clearance and international regulatory approvals.

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

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements until December 31, 2024. Our requirements for additional capital during this period will depend on many factors, including the following:

- the scope, rate of progress, results and cost of our development and engineering efforts to develop the PressureSafe and 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 nine months ended September 30, 2024, and as of the date of this report, we assessed our financial condition and concluded that based on our current and projected cash resources and commitments, as well as other factors mentioned above, there is a substantial doubt about our ability to continue as a going concern. We are planning to raise additional capital to continue our operations, as well as to explore additional avenues to increase revenues and reduce expenditures. We cannot be sure that future funding will be available to us on acceptable terms, or at all. Due to the often-volatile nature of financial markets, equity and debt financing may be difficult to obtain. We may seek to raise any necessary additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights, future revenue streams, or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through private or public equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2024, we conducted an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"). The term "disclosure controls and procedures" means controls and other procedures of a company that are designed to ensure that the information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods and that such disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of September 30, 2024, our principal Chief Executive Officer and principal Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at reasonable assurance level, as further described below.

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

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2024, 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, or the Plaintiff, a Company Director, and the Company's Chief Technology Officer in the Tel Aviv District Court of Israel by an individual who provided, on a part-time basis, certain consulting services to the Subsidiary between October 2015 through October 2016, before the acquisition of the Subsidiary by the Company. The lawsuit alleges breach of contract by the defendants based on non-payment of amounts purportedly owed to the Plaintiff in respect of the services rendered, including the market value of the Company's common stock that the Plaintiff alleges should have been issued to him in respect of his services. The suit seeks declaratory judgment that the defendants breached certain agreements with Plaintiff and claimed damages in the aggregate amount of approximately \$2.1 million based on the current exchange rate between the U.S. Dollar and the Israeli NIS.

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

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

ITEM 1A. RISK FACTORS

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

ITEM 6. EXHIBITS

Exhibit Index:

31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer (Principal Executive Officer), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
101. INS	Inline XBRL Instance Document
101. SCH	Inline XBRL Taxonomy Extension Schema
101. CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101. DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101. LAB	Inline XBRL Taxonomy Extension Label Linkbase
101. PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IR-Med, Inc.
(Registrant)

By: /s/ Ran Ziskind
Ran Ziskind
Chief Executive Officer
(Principal Executive Officer)

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

Date: November 14, 2024

Date: November 14, 2024

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: November 14, 2024

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

I, Sharon Levkoviz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IR-Med, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: November 14, 2024

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

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ran Ziskind

Ran Ziskind, Chief Executive Officer
(Principal Executive Officer)

Dated: November 14, 2024

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

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

- (i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Sharon Levkoviz

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

Dated: November 14, 2024
