

IR-MED, INC.

FORM 10-Q (Quarterly Report)

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Address	C/O ABOUDI LEGAL GROUP PLLC, 745 5TH AVE SUITE 500 NEW YORK, NY, 10151
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Fiscal Year	12/31

**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 June 30, 2022; or

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

for the transition period from _____ to _____

Commission File Number: 333-255894

IR-Med, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

83-0452269

(I.R.S. Employer
Identification No.)

**ZHR Industrial Zone
Rosh Pina Israel**

(Address of principal executive offices)

Zip Code

+ 972-4-655-5054

(Registrant's telephone number, including area code)

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

Title of each class

N/A

Trading Symbol(s)

N/A

Name of each exchange on which registered

N/A

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of August 14, 2022, 68,720,970 shares of the registrant's common stock, par value \$0.001 per share, were outstanding.

IR-MED, INC.
Form 10-Q
June 30, 2022

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Interim Unaudited Condensed Consolidated Balance Sheets

	June 30 2022	December 31 2021
	U.S dollars (in thousands)	
Assets		
Current assets		
Cash and cash equivalents	4,058	2,815
Accounts receivable	169	67
Total current assets	4,227	2,882
Non- current assets		
Long term restricted deposit	12	30
Right of use asset	192	-
Property and equipment, net	62	31
Total non-current assets	266	61
Total assets	4,493	2,943
Liabilities and Stockholders' equity		
Current liabilities		
Trade and other payables	370	395
Non-current liabilities		
Long term Lease liability	78	-
Stockholders' loans	160	177
Total non-current liabilities	238	177
Total liabilities	608	572
Stockholders' Equity		
Common Stock, par value \$0.001 per share, 250,000,000, shares authorized. 68,213,038 and 64,601,649 shares issued as of June 30, 2022, and December 31, 2021 respectively.	68	64
Additional paid-in capital	10,801	7,503
Accumulated deficit	(6,984)	(5,196)
Total Stockholders' equity	3,885	2,371
Total liabilities and stockholders' equity	4,493	2,943

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 June 30		For the six-months period ended June 30	
	2022	2021	2022	2021
	U.S dollars (in thousands)			
Research and development expenses	412	391	889	495
Marketing expenses	130	593	181	763
General and administrative expenses	429	532	754	690
Total operating loss	971	1,516	1,824	1,948
Financial expenses (income), net	(32)	6	(36)	18
Loss for the period	939	1,522	1,788	1,966
Basic and dilutive loss per common stock (in dollars)	(0.01)	,(0.02)	(0.03)	(0.03)
Weighted average number of ordinary shares	68,238,013	64,601,649	66,419,831	61,619,878

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>			
For the six-months period ended June 30, 2022					
Balance as of January 1, 2022	64,601,649	64	7,503	(5,196)	2,371
Private placement of common stock and warrants, net	3,636,364	4	3,196	-	3,200
Stock-based compensation	-	-	102	-	102
Loss for the period	-	-	-	(1,788)	(1,788)
Balance as of June 30, 2022	<u>68,238,013</u>	<u>68</u>	<u>10,801</u>	<u>(6,984)</u>	<u>3,885</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>			
For the six-months period ended June 30, 2021					
Balance as of January 1, 2021	53,586,023	54	2,827	(1,480)	1,401
Private placement of common stock and warrants, net	11,015,626	10	3,367	-	3,377
Stock-based compensation	-	-	1,067	-	1,067
Loss for the period	-	-	-	(1,966)	(1,966)
Balance as of June 30, 2021	<u>64,601,649</u>	<u>64</u>	<u>7,261</u>	<u>(3,446)</u>	<u>3,879</u>

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

Interim Unaudited Condensed Consolidated Statements of Cash Flows

	For the six-months period ended	
	June 30	June 30
	2022	2021
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	(1,788)	(1,966)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	102	1,067
Depreciation	6	2
Accrued financial expenses ,(income)	(41)	1
Decrease (increase) in accounts receivable	(102)	125
decrease in trade and other payables	(97)	(225)
Net cash used in operating activities	(1,920)	(996)
Cash flows from investing activities		
Purchase of property and equipment	(36)	(12)
Investment in restricted deposit	(9)	(12)
Net cash used in investing activities	(45)	(24)
Cash flows from financing activities		
Proceeds from private placement of common stock and warrants, net (see also note 1.B)	3,200	3,377
Net cash provided by financing activities	3,200	3,377
Effect of exchange rate changes on cash and cash equivalents	8	2
Net increase in cash and cash equivalents	1,243	2,359
Cash and cash equivalents as at the beginning of the period	2,815	1,866
Cash and cash equivalents as at the end of the period	4,058	4,225

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

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

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

IR-Med, Inc. (OTC QB: IRME, hereinafter: the “Company”) was incorporated in Nevada in 2007 and is a holding company. IR-Med Inc.’s was previously named International Display Advertising Inc, and changed its name to IR-Med Inc. in January 2021.

On December 24, 2020 IR-Med Inc. entered into a stock exchange agreement (hereinafter: the “Stock Exchange Agreement” or the “Reverse Acquisition”) with an Israeli company, IR. Med Ltd. (hereinafter: the “Subsidiary”) which was founded in May 2013. Under the Stock Exchange Agreement, IR. Med Ltd. became a wholly owned subsidiary of IR-Med, Inc. pursuant to a share exchange transaction among IR Med, Inc., IR. Med Ltd. and the former shareholders of IR. Med Ltd.

The registered office of Company and the corporate headquarters and research facility of the Subsidiary are located in Rosh Pina, Israel.

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

- B.** The Company is in its development stage and does not expect to generate significant revenue until such time as it shall have completed the design and development of its initial product candidates and obtained the requisite approvals to market the product. During the six months ended June 30, 2022, the Company incurred losses of \$1,788 thousand and had a negative cash flow from operating activities of \$1,920 thousand. The accumulated deficit as of June 30, 2022 is \$ 6,984 thousand.

Management’s plans regarding these matters include continued development and marketing of its product candidates, as well as seeking additional financing arrangements. In April 2022, the Company raised \$3,200 thousand from the private placement. In addition, during July 22 the company raised an additional \$425,000 (see note 5) from the private placement to accredited investors of the Company’s securities on the same terms and conditions as the April 2022 raise.

The Company Managements believes that its current cash resources are sufficient for the operations of the next 12 months

- C.** In March 2020, the World Health Organization declared the coronavirus (COVID-19) outbreak a global pandemic. To date, the impact of the pandemic on the Company’s operations has been mainly limited to a temporary office closure in the context of a government-mandated general lockdown that had no significant impact on operations. Based on the information in its possession, the Company estimates that as of the date of approval of the financial statement, the Covid-19 pandemic is not expected to affect the Company’s operations. However, the Company is unable to assess with certainty the extent of future impact, in part due to the uncertainty regarding the duration of the Covid-19 pandemic, its force and its effects on the markets in which the Company operates and additional measures that the government may adopt.

Note 2 - Interim Unaudited Financial Information

The accompanying interim unaudited financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (“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, 2021.

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 six months period ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending December 31, 2022.

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the Interim Financial Statements, and the reported amounts of expenses during the reporting period. Significant items subject to such estimates and assumptions 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, 2021, excluding the following:

Leases

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, “Leases” (Topic 842), which requires lessees to recognize assets and liabilities for leases with lease terms of more than 12 months. Consistent with current GAAP, the recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee primarily depends on its classification as a finance or operating lease. However, unlike previous GAAP, which required only capital leases to be recognized on the balance sheet, the new guidance required both types of leases to be recognized on the balance sheet. The ASU is effective for interim and annual periods beginning after December 15, 2021, with early adoption permitted. A modified retrospective transition approach is required in applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. If an entity chooses the second option, the entity must recast its comparative period financial statements and provide disclosures required by the new standard for the comparative periods.

The Company adopted the new standard on January 1, 2022, using the effective date as its date of initial application. Consequently, financial information will not be updated and disclosures required under the new standard will not be provided for dates and periods before January 1, 2022.

The Subsidiary is a lessee in several noncancellable operating leases, primarily for transportation. The Company accounts for leases in accordance with Topic 842, Leases. The Company determines if an arrangement is or contains a lease at contract inception. The Company recognizes a right-of-use (ROU) asset and a lease liability at the lease commencement date. For operating leases, the lease liability is initially and subsequently measured at the present value of the unpaid lease payments at the lease commencement date.

Note 3 - Significant Accounting Policies (cont'd)

Key estimates and judgments include how the Company determines (1) the discount rate it uses to discount the unpaid lease payments to present value, (2) lease term, and (3) lease payments.

Topic 842 requires a lessee to discount its unpaid lease payments using the interest rate implicit in the lease or, if that rate cannot be readily determined, its incremental borrowing rate. Generally, the Company cannot determine the interest rate implicit in the lease because it does not have access to the lessor's estimated residual value or the amount of the lessor's deferred initial direct costs. Therefore, the Company generally uses its incremental borrowing rate as the discount rate for the lease. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms. Because the Company does not generally borrow on a collateralized basis, it uses the interest rate it pays on its noncollateralized borrowings as an input to deriving an appropriate incremental borrowing rate, adjusted for the amount of the lease payments, the lease term, and the effect on that rate of designating specific collateral with a value equal to the unpaid lease payments for that lease.

- Lease payments included in the measurement of the lease liability comprise of the following:
 - Fixed payments, including in-substance fixed payments, owed over the lease term (which includes termination penalties the Company would owe if the lease term assumes the Company's exercise of a termination option);
 - Variable lease payments that depend on an index or rate, initially measured using the index or rate at the lease commencement date;

The Right Of Use (ROU) asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for lease payments made at or before the lease commencement date, plus any initial direct costs incurred less any lease incentives received. For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Variable lease payments associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented as operating expense in the Company's consolidated statements of income in the same line item as expense arising from fixed lease payments (operating leases) or amortization of the ROU asset (finance leases). ROU assets for operating and finance leases are periodically reduced by impairment losses. The Company uses the long-lived assets impairment guidance in ASC Subtopic 360-10, Property, Plant, and Equipment – Overall, to determine whether an ROU asset is impaired, and if so, the amount of the impairment loss to recognize. The Company monitors for events or changes in circumstances that require a reassessment of one of its leases. When a reassessment results in the remeasurement of a lease liability, a corresponding adjustment is made to the carrying amount of the corresponding ROU asset unless doing so would reduce the carrying amount of the ROU asset to an amount less than zero. In that case, the amount of the adjustment that would result in a negative ROU asset balance is recorded in profit or loss. Operating lease ROU assets are presented as operating lease right of use assets on the consolidated balance sheet. The current portion of operating lease liabilities is included in trade and other payables and the long-term portion is presented separately as operating lease liabilities on the consolidated balance sheet.

The Company recognizes the lease payments associated with its short-term transportation equipment leases as an expense on a straight-line basis over the lease term. Variable lease payments associated with these leases are recognized and presented in the same manner as for all other Company leases.

Note 4 – Stock options plan

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

As of June 30, 2022, the Company awarded to its employees and service providers options to purchase in the aggregate up to 9,442,843 shares of Common Stock, of which options for 8,762,843 shares were at an exercise price of US\$ 0.32 per share, options for 480,000 shares were at an exercise price of 0.01 per share and options for 200,000 shares were at an exercise price of \$0.64 per share. Of the options granted, options for 6,069,579 shares were vested upon grant and the remaining balance have a vesting period ranging between one to five years. The options are exercisable for periods ranging between three to ten years from the vesting date. The grant was approved following the adoption of the 2020 incentive stock plan (hereinafter the “Plan”) by the Company on December 23, 2020 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 \$102 thousands during the six-month period ended June 30, 2022.

The stock-based compensation expenses for the six-month period ended June 30, 2022 were recognized in the statements of operations as follows; \$47 thousands were recorded as research and development expenses, and \$55 thousands were recorded as general and administrative expenses (\$1,022 thousands were recognized for the six-month period ended June 30, 2021).

The stock-based compensation expenses for the three-month period ended June 30, 2022 were recognized in the statements of operations as follows; \$26 thousands were recorded as research and development expenses, and \$23 thousands were recorded as general and administrative expenses (\$1,022 thousands were recognized for the three-month period ended June 30, 2021).

	For the six months ended June 30, 2022
Dividend yields (see (A) below)	0.0%
Share price (in U.S. dollar) (see (B) below)	0.26-0.53
Expected volatility (see (C) below)	82.77%-142.57%
Risk-free interest rates (see (D) below)	0.17%-2.63%

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 4 – Stock options plan (cont'd)

- A. The Company used 0% as its expected dividend yield, based on historic policies and future plans.
- B. The Company's common stock is quoted on the Over the Counter ("OTC"), QB tier. However, the Company considers its share price as it is traded on OTC to not be an appropriate representation of fair value, since it is not traded on an active market. The Group determined that the market is inactive due to low level of activity of the 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 the April 2021 Private placement units of Common Stock and Warrants at a per unit purchase price of \$0.64 and on April 2022 Private placement units of Common Stock and Warrants at a per unit purchase price of \$0.88. In order to evaluate the price per share, the Warrant value has been deducted from the total unit price.
- C. As the Company is at its early stage of operation, there is not sufficient historical volatility for the expected term of the stock options. Therefore, the Company uses an average historical share price volatility based on an analysis of reported data for a peer group of comparable publicly traded companies which were selected based upon industry similarities.
- D. The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Note-5 -Subsequent events

During July 2022 the Company entered into Subscription Agreements with four Investors pursuant to which the Company issued 482,957 shares of our common stock at a per share price of \$0.88 and warrants to purchase up to an additional 482,957 shares of common stock at a per share exercise price of \$1.10. The Company is entitled to expedite the Warrant exercise period for all or a part of the then outstanding Warrants by written notice to the holders if the publicly traded price of the Company's Common Stock equals or exceeds \$2.50 per share (which amount may be adjusted for certain capital events, such as stock splits, as described herein) and the corresponding average daily trading volume during such period shall equal or exceed 75,000 shares, in each case for the forty (40) consecutive trading days. The Company received aggregate gross proceeds of \$425,000.

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

Forward-looking Statements

This Quarterly Report on Form 10-Q contains certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws, and is subject to the safe-harbor created by such Act and laws. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “potential” or “continue,” the negative of such terms, or other variations thereon or comparable terminology. The statements herein and their implications are merely predictions and therefore inherently subject to known and unknown risks, uncertainties, assumptions and other factors that may cause actual results, performance levels of activity, or our achievements, or industry results to be materially different from those contemplated by the forward-looking statements. Except as required by law, we undertake no obligation to release publicly the result of any revision to these forward-looking statements that may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Further information on potential factors that could affect our business is described under the heading “Risk Factors” in in Part I, Item 1A, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 as filed with the Securities and Exchange Commission, or the SEC, on March 31, 2022. As used in this quarterly report, the terms “we”, “us”, “our”, the “Company” and “IR-Med” mean IR-Med, Inc. and our wholly-owned subsidiary IR. Med Ltd. unless otherwise indicated or as otherwise required by the context.

Overview

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

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

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

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

The global diagnostics market is driven in large part by solutions that can be applied in healthcare settings, as these tools will drive decisions regarding specific treatments and the associated outlays. However, despite advances in medical imaging and other diagnostic tools, misdiagnosis remains a common occurrence. We believe that offering additional Decision Support Systems (DSS) tools may improve diagnoses and outcomes through the adoption of AI-based decision support tools.

We are currently working on completing the development of first prototype of the *PressureSafe* device, incorporating a more advanced technology platform. We expect to complete the development of the *PressureSafe* prototype in the second quarter of 2022 followed by usability studies. In June 2022, IR Med. Ltd., our wholly owned subsidiary, entered into a study agreement with Beit Rivka, a Large Geriatric Hospital in Israel associated with Clalit, the largest Health Insurance Fund in Israel, to conduct a usability study of *Pressuresafe*.

Recent Developments

On April 11, 2022, we entered into a Subscription Agreements (the “Subscription Agreement”) with certain investors (each an “Investor” and, collectively, the “Investors”), pursuant to which we agreed to issue and sell, in a private placement (the “2022 Offering”), 3,636,364 shares of our common stock at a per share price of \$0.88 and warrants to purchase up to an additional 3,636,364 shares of common stock at a per share exercise price of \$1.10. The Company received aggregate gross proceeds of \$3,200,000. The Warrants are exercisable for two years from the date of issuance and entitle the holders to purchase up to 3,636,364 shares of Common Stock. The Warrants have an exercise price of \$1.10 per share. However, the Company is entitled to expedite the Warrant exercise period for all or a part of the then outstanding Warrants by written notice to the Investors if the publicly traded price of the Company’s Common Stock equals or exceeds \$2.50 per share (which amount may be adjusted for certain capital events, such as stock splits, as described herein) and the corresponding average daily trading volume during such period shall equal or exceed 75,000 shares, in each case for the forty (40) consecutive trading days.

On April 25, 2022, we received notice that Dr. Rom Eliaz would be resigning from his role as Chief Executive Officer to pursue personal interests. Dr. Eliaz’s resignation was effective as of April 30, 2022.

On May 2, 2022, Moshe Gerber was appointed as Chief Executive Officer, effective as of May 8, 2022.

During July 2022 we entered into Subscription Agreements with four Investors under the 2022 Offering on the same terms and conditions specified above where we issued 482,957 shares of our common stock at a per share price of \$0.88 and warrants to purchase up to an additional 482,957 shares of common stock at a per share exercise price of \$1.10. We received aggregate gross proceeds of \$425,000.

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 and we do not expect to generate revenues from product sales for the foreseeable future.

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 through 2023 as we continue to develop our product candidates. We are unable, with any certainty, to estimate either the costs or the timelines in which those expenses will be incurred. Our current development plans focus on the development of our *PressureSafe* and *Nobiotics* diagnostic devices. The design and development of these devices will consume a large proportion of our current, as well as projected, resources.

Our research and development costs include costs are comprised of:

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

Marketing

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

General and Administrative Expenses

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

Financial Expenses

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

Comparison of the Three and Six Months Ended June 30, 2022 to the Three and Six Months Ended June 30, 2021

	For the three months ended June 30		For the six months ended June 30	
	2022	2021	2022	2021
	U.S dollars (in thousands)			
Research and development expenses	412	391	889	495
Marketing expenses	130	593	181	763
General and administrative expenses	429	532	754	690
Total operating expenses	971	1,516	1,824	1,948
Financial expenses (income), net	(32)	6	(36)	18
Loss for the period	939	1,522	1,788	1,966

Revenues. We have not recorded any revenues to date.

Research and Development Expenses- Research and development expenses consist of salaries and related expenses, consulting fees, service providers', costs, and overhead expenses. Research and development expenses increased from \$391,000 and \$495,000 for the three and six months ended June 30, 2021, respectively, to \$412,000 and \$889,000, respectively, for the corresponding periods in 2022. The Company's research and development program intensified in the third quarter of 2021. The increase in each of the three and six months periods resulted primarily from the recruitment of employees, increased use of third party contractors for further research and development activities and the initiation of usability studies for our *PressureSafe* device. These increases were partially offset by the lower non-cash expenses relating to stock based compensation to employees and service providers which were granted in June 2021.

Marketing Expenses – Marketing expenses consist primarily of salaries and professional services. Marketing Expenses decreased from \$593,000 and \$763,000 for the three and six months ended June 30, 2021, respectively, to \$130,000 and \$181,000, respectively, for the corresponding periods in 2022. The decrease in marketing expenses resulted primarily from decrease of non-cash expenses resulting from stock based compensation to employees and service providers that were awarded in June 2021.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and related expenses and other non-personnel related expenses such as legal and accounting related expenses. General and Administrative expense decreased from \$532,000 for the three months ended June 30, 2021 to \$ 429,000 for the three months ended June 30, 2022. The decrease in general and administrative expenses resulted primarily from lower non-cash expenses relating to the stock based compensation to employees and service providers awarded in June 2021, which were partially offset by an increase expenses related to the retention of additional service providers. General and Administrative expenses increased from \$690,000 for the six months ended June 30, 2021, to \$754,000 for the six months ended June 30, 2022. The increase in general and administrative expenses resulted primarily from increased expenses related to service providers to support our general and administrative operation, increase in salaries and related expenses which were partially offset by the lower non-cash expenses in 2022 attributable to the options awards in June 2021 to employees and service providers.

Loss. Loss for the six months ended June 30, 2022 was \$1,788,000, and is primarily attributable to research and development, marketing activities, general and administrative expenses

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. Between December 24, 2020 and April 10, 2021, we raised aggregate gross proceeds in the approximate amount of \$5.83 million. between April and July 2022, we raised an additional \$3,625,000 from sales of our equity and equity linked securities.

As of June 30, 2022, we had a total of \$4,058,000 in cash resources and approximately \$608,000 of liabilities, consisting of \$370,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the three and six months ended June 30, 2022 respectively (in thousands):

	For the six months ended	
	June 30	
	2022	2021
	U.S dollars (in thousands)	
Net cash used in operating expenses	(1,920)	(996)
Net cash used in investment activities	(45)	(24)
Net cash provided by financing activities	3,200	3,377

We have experienced operating losses since its inception and had a total accumulated deficit of \$6,984,000 as of June 30, 2022. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception and in the six months ended June 30, 2022. These losses have resulted in significant cash used in operations. During the six months ended June 30, 2022, our cash used in operations was approximately \$1,920,000, compared to \$996,000 during the corresponding period in 2021. We need to continue and intensify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes and pursue FDA clearance and international regulatory approvals. As we continue to conduct these activities, we expect the cash needed to fund operations to increase significantly over the next several years.

Under the private placement of our securities that we undertook between December 2020 and April 2021, we entered into a securities purchase agreement with certain accredited investors providing for the issuance and sale to such investors of an aggregate of 18,221,876 shares of our Common Stock and warrants for an additional 9,110,938 shares of our Common Stock, exercisable through December 24, 2023, at a per share exercise price of \$0.64. After deducting for offering related expenses, the aggregate net proceeds from the initial closing of the 2020 Private Placement were approximately \$5,446,000.

Under the private placement of our securities which we commenced in April 2022, we entered into a securities purchase agreement with six accredited investors providing for the issuance and sale to such investors of an aggregate of 4,119,321 shares of our Common Stock and warrants for an additional 4,119,321 shares of our Common Stock, exercisable through 2024, at a per share exercise price of \$1.10. However, the Company is entitled to expedite the Warrant exercise period for all or a part of the then outstanding Warrants by written notice to the Investors if the publicly traded price of the Company's Common Stock equals or exceeds \$2.50 per share (which amount may be adjusted for certain capital events, such as stock splits, as described herein) and the corresponding average daily trading volume during such period shall equal or exceed 75,000 shares, in each case for the forty (40) consecutive trading days. The aggregate gross proceeds from the April 2022 Private Placement were approximately \$3,625,000.

Notwithstanding the above referenced capital raises, we will need to obtain additional funding in order to fully realize 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 for the next twelve months. Our requirements for additional capital during this period will depend on many factors, including the following:

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

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 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

Not Applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2022, we conducted an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, regarding the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the “Exchange Act”). The term “disclosure controls and procedures” means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the requisite time periods and that such disclosure controls and procedures were effective to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is accumulated and communicated to its management, including its principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective at reasonable assurance level due to a material weakness in internal control over financial reporting, 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. As disclosed in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021, our management concluded that our internal control over financial reporting was not effective at December 31, 2021. 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. The limitation of our internal control over financial reporting was due to the applied risk-based approach which is indicative of many small companies with limited number of staff in corporate functions implying:

- (i) Lack of information technology controls to maintain appropriate access rights and backup procedures; and
- (ii) Insufficient segregation of duties with control objectives

Our management believes the weaknesses identified above have not had any material effect on our financial results.

We are committed to maintaining a strong internal control environment and believe that our remediation efforts specified in Item 9A of our Annual Report on Form 10-K for the year ended December 31, 2021 represent significant improvements in our control environment. We expect that our remediation efforts will continue through 2022 and into 2023, although the material weakness will not be considered remediated until the applicable internal controls operate for a sufficient period, and management has concluded, through testing, that these controls are operating effectively.

From the beginning of the fourth quarter of 2021, management introduced internal control and review procedures including the hiring of a Sarbanes and Oxley (SOX) expert in order to remediate the material weaknesses in internal controls referred to above.

Changes in Internal Control Over Financial Reporting

During the quarter ended June 30, 2022, 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

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

ITEM 1A. RISK FACTORS

An investment in the Company's Common Stock involves a number of very significant risks. You should carefully consider the risk factors included in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the SEC on March 31, 2022, in addition to other information contained in our reports and in this quarterly report in evaluating the Company and its business before purchasing shares of our Common Stock. There have been no material changes to our risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2021..

ITEM 2. UNREGISTERED SALES OF SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION:

None

ITEM 6. EXHIBITS

Exhibit Index:

- 4.1 [Form of Warrant Agreement entered into by the IR-Med, Inc. and certain investors in April 2022 \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 14, 2022\).](#)
- 10.1 [Form of Subscription Agreement entered into by IR-Med, Inc. and certain investors during April – July 2022 \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on April 14, 2022\).](#)
- 10.2 [Employment Agreement between IR. Med Ltd and Moshe Gerber dated May 2, 2022 \(incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on May 10, 2022\).](#)
- 31.1 [Certification of Chief Executive Officer \(Principal Executive Officer\) pursuant to Rule 13a-14\(a\) of the Securities Exchange Act of 1934](#)
- 31.2 [Certification of Chief Financial Officer \(Principal Financial and Accounting Officer\) pursuant to Rule 13a-14\(a\) of the Securities Exchange Act of 1934](#)
- 32.1 [Certification of Chief Executive Officer \(Principal Executive Officer\), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2 [Certification of Chief Financial Officer \(Principal Financial and Accounting Officer\) pursuant to Rule 13a-14\(a\) of the Securities Exchange Act of 1934](#)

- 101.INS Inline XBRL Instance Document
- 101.SCH Inline XBRL Taxonomy Extension Schema
- 101.CAL Inline XBRL Taxonomy Extension Calculation Linkbase
- 101.DEF Inline XBRL Taxonomy Extension Definition Linkbase
- 101.LAB Inline XBRL Taxonomy Extension Label Linkbase
- 101.PRE Inline XBRL Taxonomy Extension Presentation Linkbase

- 104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith

SIGNATURES

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

IR-Med, Inc.
(Registrant)

By: */s/ Moshe Gerber*

Moshe Gerber
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Sharon Levkoviz*

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

Date: August 15, 2022

Date: August 15, 2022

I, Moshe Gerber, certify that:

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

By: */s/ Moshe Gerber*

Moshe Gerber, Chief Executive Officer
(Principal Executive Officer)

Date: August 15, 2022

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: August 15, 2022

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350**

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 June 30, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Moshe Gerber

Moshe Gerber, Chief Executive Officer
(Principal Executive Officer)

Dated: August 15, 2022

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
18 U.S.C. SECTION 1350**

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 June 30, 2022 (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: August 15, 2022
