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IR-MED, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/15/21 for the Period Ending 09/30/21

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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, 2021; 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	**83-0452269**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
ZHR Industrial Zone Rosh Pina Israel	
(Address of principal executive offices)	Zip Code

+ 972-4-655-5054

(Registrant's telephone number, including area code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
N/A	N/A	N/A

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☒
		Emerging growth company	☐

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

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

As of November 15, 2021, 64,601,649 shares of the registrant's common stock, par value $0.001 per share, were outstanding.

IR-MED, INC.
Form 10-Q
September 30, 2021

Interim Unaudited Condensed Consolidated Balance Sheets

	September 30 2021	December 31 2020
	U.S dollars (in thousands)	
Assets		
Current assets		
Cash and cash equivalents	**3,550**	1,866
Short term restricted deposit	**12**	-
Accounts receivable	**109**	218
Total current assets	**3,671**	2,084
Non- current assets		
Property and equipment, net	**25**	6
Total assets	**3,696**	2,090
Liabilities and Stockholders' equity		
Current liabilities		
Trade and other payables	**238**	523
Non-current liabilities		
Stockholders' loans	**170**	166
Total liabilities	**408**	689
Stockholders' Equity		
Common Stock, par value $0.001 per share, 250,000,000, shares authorized as of September 30, 2021 and December 31, 2020; 64,601,649 and 53,586,023 shares issued as of September 30, 2021 and December 31, 2020, respectively	**64**	54
Additional paid-in capital	**7,400**	2,827
Accumulated deficit	**(4,176)**	(1,480)
Total Stockholders' equity	**3,288**	1,401
Total liabilities and stockholders' equity	**3,696**	2,090

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	
	2021	**2020**	**2021**	**2020**
	U.S dollars (in thousands)			
Research and development expenses	**374**	46	**869**	192
Marketing expenses	**61**	-	**824**	-
General and administrative expenses	**287**	34	**977**	145
Total operating loss	**722**	80	**2,670**	337
Financial expenses, net	**8**	9	**26**	11
Loss for the period	**730**	89	**2,696**	348
Basic and dilutive loss per common stock (in dollars)	**(0.01)**	*(0.003)	**(0.04)**	*(0.01)

(*) Share capital was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company).

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

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

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the nine-months period ended September 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	-	-	**1,206**	-	**1,206**
Loss for the period	-	-	-	**(2,696)**	**(2,696)**
Balance as of September 30, 2021	**64,601,649**	**64**	**7,400**	**(4,176)**	**3,288**

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' deficit
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the nine-months period ended September 30, 2020					
Balance as of January 1, 2020	*30,185,183	*29	*618	(728)	*(81)
Issuance of common stock, net	343,536	1	80	-	81
Loss for the period	-	-	-	(348)	(348)
Balance as of September 30, 2020	30,528,539	30	698	(1,076)	*(348)

(*) Share capital was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company) and adoption of ASU 2018-07

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

Interim Unaudited Condensed Consolidated Statements of Changes in Equity (Deficit)

	Common Stock		Additional paid-in	Accumulated	Total stockholders'
	Number of Shares	Amount	Capital	deficit	equity
		U.S dollars (in thousands)			
For the three-months period ended September 30, 2021					
Balance as of July 1, 2021	**64,601,649**	**64**	**7,261**	**(3,446)**	**3,879**
Stock-based compensation	**-**	**-**	**139**	**-**	**139**
Loss for the period	**-**	**-**	**-**	**(730)**	**(730)**
Balance as of September 30, 2021	**64,601,649**	**64**	**7,400**	**(4,176)**	**3,288**

	Common Stock		Additional paid-in	Accumulated	Total stockholders'
	Number of Shares	Amount	Capital	deficit	deficit
		U.S dollars (in thousands)			
For the three-months period ended September 30, 2020					
Balance as of July 1, 2020	*30,185,183	*29	*618	(987)	*(340)
Issuance of common stock, net	*343,356	1	80		81
Loss for the period	**-**	**-**	**-**	(89)	(89)
Balance as of September 30, 2020	*30,528,539	*30	*698	(1,076)	*(348)

(*) Share capital was retroactively adjusted using the exchange ratio established pursuant to the Stock Exchange Agreement to reflect the capital of the legal entity (the Parent Company) and adoption of ASU 2018-07

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 2021	**September 30 2020**
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	**(2,696)**	(348)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	**1,161**	-
Depreciation	**3**	1
Compensation related to warrants issued to service providers	**-**	25
Increase in financial expenses	**3**	8
Decrease in accounts receivable	**109**	3
Increase (decrease) in trade and other payables	**(240)**	32
Net cash used in operating activities	**(1,660)**	(279)
Cash flows from investing activities		
Purchase of property and equipment	**(22)**	-
Investment in restricted deposit	**(12)**	-
Net cash used in investing activities	**(34)**	-
Cash flows from financing activities		
Proceeds from issuance of common stock, net	**-**	81
Proceeds from private placement of common stock and warrants, net (see also note 1.B)	**3,377**	-
Net cash provided by financing activities	**3,377**	81
Effect of exchange rate changes on cash and cash equivalents	**1**	1
Net increase (decrease) in cash and cash equivalents	**1,684**	(197)
Cash and cash equivalents as at the beginning of the period	**1,866**	235
Cash and cash equivalents as at the end of the period	**3,550**	38

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 Pink: IRME, hereinafter: the "Parent Company") was incorporated in Nevada in 2007 and is a holding company. IR-Med Inc. 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 "Company" or the "Subsidiary") which was founded in May 2013. The Parent Company and its Subsidiary are referred in these consolidated financial statements as the "Group". According to 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 IR-Med, Inc. and the corporate headquarters and research facility of IR. Med Ltd. are located in Rosh Pina, Israel.

The Group is an innovative development stage medical device company focused on leveraging Infra-Red (IR) and Artificial Intelligence (AI) technologies to provide solutions to currently unmet medical needs. The Company's current products in development are non-invasive and designed to address the medical needs of large and growing patient populations by improving the efficacy and safety of treatment, reducing the widespread reliance on antibiotics, offering more accurate diagnosis and optimizing the delivery of medical services.

B. The Group is in its development stage and does not expect to generate significant revenue until such time as the Group shall have completed the design and development of its initial product candidate and obtained the requisite approvals to market the product. During the nine-months period ended September 30, 2021, the Group incurred losses of US$ 2,696 thousand and had negative cash flows from operating activities of US$1,660 thousand. The accumulated deficit as of September 30, 2021 is US$ 4,176 thousand.

Management's plans regarding these matters include continued development and marketing of its products, as well as seeking additional financing arrangements. Although management continues to pursue these plans, there is no assurance that the Group will be successful in raising the needed capital from revenues or financing on commercially acceptable terms. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Between January 2021 and April 2021, the Company raised in the aggregate $3,377,005 net of issuance cost of $147,345. According to the subscription agreements, the Group issued to the Investors 5,507,813 units of its securities (hereinafter: "Unit" and collectively the "Units") at a price per Unit of $0.64. Each Unit is comprised of two shares of IR-Med Inc.'s common stock and one warrant to purchase an additional share of IR-Med Inc.'s common stock, exercisable for a three years period from the date of issuance at a per share exercise price of $0.64, subject to certain limited adjustments.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 1 – General (cont'd)

C. On November 9, 2021 United States Securities and Exchange Commission (the "SEC") declared IR-Med's resale Registration Statement on Form S-1 (the "Registration Statement") effective IR-Med became a SEC reporting company upon effectiveness of the Registration Statement. IR- Med is not selling any securities under the Registration Statement. Rather, the Registration Statement relates to the potential resale, from time to time, of securities of IR-Med by certain of its security holders. IR-Med will not receive any proceeds from any sale of securities by the selling security holders pursuant to the Registration Statement. The S-1 registration includes approximately 38 million shares, of which approximately 9 million of are shares investor warrants exercisable at $0.64 per share.

D. 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 the Company's operations. Based on the information in its possession, the Company estimates that as of the date of approval of the financial statements, 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 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, 2020.

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 nine months period ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021.

Use of Estimates:

The preparation of financial statements in conformity with GAAP requires management to

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 2– Interim Unaudited Financial Information (cont'd)

make estimates and assumptions that affect the assets, liabilities, costs and expenses that are reported in the Interim Financial Statements and accompanying disclosures. These estimates are based on management's best knowledge of current events, historical experience, actions that the Company may undertake in the future and on various other assumptions that are believed to be reasonable under the circumstances. As a result, actual results may be different from these 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, 2020, excluding the following:

Stock Option Plan

The Group recognizes all employee and nonemployee stock-based compensation as a cost in the consolidated financial statements. For awards with a graded vesting schedule, the Company uses the graded vesting attribution approach to recognize compensation cost over the vesting period.

The Group estimates grant date fair value using the Black-Scholes-Merton option-pricing model and estimates the number of forfeitures expected to occur.

Note 4 – Stock options plan

The Parent Company awarded to the Company's employees and service providers options to purchase up to 7,534,843, 180,000 and 280,000 common stock par value $0.001 per share (the "Common Stock") of the Company at an exercise price of US$ 0.32, 0.01 and $0.64 per option respectively. Of these, options for 5,729,579 shares were vested upon grant and the vesting period of the remaining options range between one-five years and option exercise period expires between three-ten years from the vesting date. The grant was approved following the adoption of the 2020 incentive stock plan (hereinafter the "Plan") by the Parent Company on December 23, 2020 and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021. The Group recorded in the statement of operations a non-cash expense of $1,161 thousands and $139 thousands during the nine and three-months periods ended September 30, 2021, respectively. The stock-based compensation expenses for the nine-months period ended September 30, 2021 were recognized in the statements of operations as follows; $218 thousands were recorded as research and development expenses, $470 thousands were recorded as marketing expenses and $473 thousands were recorded as general and administrative expenses.

The following table sets forth information about the weighted-average fair value of options granted to employees and service providers during the nine-month period ended

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

Note 4 – Stock options plan (cont'd)

September 30, 2021, using the Black- Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

	For the nine months period ended September 30, 2021
Dividend yields (Note 4A)	0.0%
Share price (in U.S. dollar) (Note 4B)	0.26
Expected volatility (Note 4C)	82.77%-142.57%
Risk-free interest rates (Note 4D)	0.18%-1.7%
Expected life (in years)	1.5-14.79

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

B. The Parent-Company common stocks are quoted on the Over the Counter ("OTC"). However, the Group considers its share price as it is traded on OTC to not be an appropriate representation of fair value, since it is not traded on an active market. The Group determined that the market is inactive due to low level of activity of the Parent Company's Common Stock, stale or non-current price quotes and price quotes that vary substantially either over time or among market makers. Consequently, the price of the Parent-Company's Common Stock has been determined based on the April 2021 Private placement units of Common Stock and Warrants at a per unit purchase price of $0.64. 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 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.

D. 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.

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 our registration statement on Form S-1 as filed with the Securities and Exchange Commission, or the SEC, on October 28, 2021As 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

Through its subsidiary IR-Med Ltd, the Company is an innovative development stage medical device company that utilizes Infra-Red light spectroscopy (IR) combined with Artificial Intelligence (AI) technologies to address currently unmet medical needs. Our 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 detection, reducing healthcare expenses and reducing the widespread reliance on antibiotics, optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

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 improved diagnoses and outcomes are achievable through the adoption of AI-based decision support tools.

Our initial focus is on the development of diagnostic supporting solutions utilizing our proprietary platform for the pre-emptive diagnosis of pressure injuries (PI) and of mid-ear infections detection Our current business plan focuses on two principal medical devices currently in development:

1. *PressureSafe* — a handheld optical monitoring device that is being developed to support early detection of pressure injuries (PI) to the skin and underlying tissue, primarily caused by prolonged pressure associated with bed confinement; and

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

Our product candidates are in various stages of development.

We are currently working on completing the development of first preliminary 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.

The *Nobiotics* device is planned to be an otoscope for supporting noninvasive detection of otitis media (ear infection). The device is in initial stages of development as an ear examination device.

Background on Pressure Injuries

PI is a significant challenge to care providers throughout the world. Failure to identify and treat PI is potentially fatal, with an estimated 60,000 mortalities from PI in the United States each year[24]. Prevention of PI is a measure of quality in all healthcare settings. There are three main healthcare setting most prone to high frequency of PI - hospital settings, nursing homes and long term homecare.

To address the preemptive diagnosis of PI, we are developing a proprietary, user-friendly, non-invasive and real-time optical monitoring device combined with an AI based capabilities for pre-emptive detection of PI and for enhanced management of PI in different settings. The device is being designed to address the main diagnostic problems of identifying PI and differentiating between two main groups of PIs— Deep Tissue Injury (DTI) and Stage 1 PI (the first stage is most difficult to detect) three to four days before the PI becomes visible to the naked eye. The device is being designed to operate regardless of the skin type and skin complexion of the patient, which is a critical advantage. The device is being designed to include a disposable component, which will be attached to the tip of the device, where the infra-red light source and light collector are located, which is intended to come into contact with the individual's skin surface. The disposable unit will be specific to each individual; hence any potential for cross infection of individuals is avoided. The disposable will be designed using high clarity polymer, to allow high light visibility through the disposable.

Preliminary clinical studies of PressureSafe proof of concept (POC) unit have been carried out in Israel and additional clinical useability studies with PressureSafe prototype are expected in the first half of 2022.

Ear Infection Background

An ear infection is an inflammation of the middle ear, usually caused by bacteria or a virus, which occurs together with fluid builds up behind the eardrum. Three out of four children will have at least one ear infection by their third birthday[25]. In fact, ear infections are the most common reason parents bring their child to a doctor.

The presence of middle ear fluid is the key diagnostic marker for the two most common pediatric ear diseases, acute otitis media (AOM) and otitis media with effusion (OME)[26].

AOM, known commonly as an "ear infection" is characterized by the presence of infected fluid in the middle ear and results in symptoms of fever and ear pain. It is a leading cause of pediatric healthcare visits, and although many cases can resolve without antibiotics, complications may include eardrum perforation, mastoiditis, facial nerve palsy, or meningitis.

OME is the presence of middle ear fluid without signs of an acute infection and affects up to 80% of children. Although OME has few overt symptoms, making diagnosis more difficult, it is associated with speech delay, sleep disruption, poor school performance, balance issues, and a higher likelihood of developing AOM.

The simplest way for a doctor to diagnose an ear infection is by using an otoscope, a lighted instrument, to view and assess the eardrum. A red, bulging eardrum indicates an infection.

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[24] Market Research Future, 2020. *Global Ear Infection Treatment Market: Information By Type (Middle Ear, Outer Ear, Inner Ear), By Pathogen (Bacteria, Virus), By Treatment (Surgery, Medication), By End User (Hospitals, ENT Clinics) and Region (Americas, Europe, Asia-Pacific and the Middle East & Africa) - Forecast till 2027*.

[25] Thomas, J., Berner, R., Zahnert, T. and Dazert, S., 2014. Acute Otitis Media. *Deutsches Aerzteblatt Online*,.

26 Thomas, J., Berner, R., Zahnert, T. and Dazert, S., 2014. Acute Otitis Media. *Deutsches Aerzteblatt Online*,.

Other methods a doctor can use include: (i) Pneumatic otoscope, which blows a puff of air into the ear canal, this allows the doctor to observe the eardrum movement. A normal eardrum will move back and forth more easily than an eardrum with fluid behind it; and (ii) Tympanometry, this is soft plug that contains a miniature microphone and speaker as well as a device that varies air pressure in the ear, measuring how flexible the eardrum is at different pressures.

Many doctors will prescribe an antibiotic, such as amoxicillin, to be taken over seven to 10 days. The doctor also may recommend over-the-counter pain relievers such as acetaminophen or ibuprofen, also as eardrops, to help with fever and pain.

If the doctor is not able to make a definite diagnosis of OME and the child does not have severe ear pain or a fever, the doctor may suggest waiting a day or so to see if the earache goes away. Today, when a child has ear pain, the doctor will check the ear but unless there is a clear visible need, he/she will probably not give any treatment beside pain relief - due to simple fact that he/she cannot determine if the infection is Viral – which no antibiotic should be given or Bacterial which will require antibiotic treatment.

Nobiotics

The Nobiotics device is planned to be an otoscope for supporting noninvasive detection of otitis media (ear infection). The device is in initial stages of development as an ear examination device that will give the physician an immediate indication if the infection is from a Viral or Bacterial source. The device works on a similar IR-spectrographic analysis method as being developed in the PressureSafe device. The Nobiotics otoscope is based on infrared light reflection and absorption by the effluents behind the ear drum. Reflected (and absorbed infrared light) is compared continuously to the emitted light. Light changes as it penetrated and reflected through different tissues.

Otoscopes are considered a required device by any physicians performing physical diagnoses. Target customers for the Nobiotics device are general practitioners (GPs), pediatricians and ear nose and throat (ENT) specialists.

Recent Developments

Reverse Merger

On September 3, 2020, IR-Med Inc. and IR-Med Ltd. and the former stockholders of IR-Med Ltd. entered into a Securities Exchange Agreement (the "Acquisition") pursuant to which the stockholders of IR-Med Ltd. contributed all of their equity interests in IR-Med Ltd. to IR-Med Inc. in exchange for shares of IR-Med common stock, which resulted in IR-Med Ltd. becoming a wholly owned subsidiary of IR-Med Inc., which we refer to as the Acquisition. The Acquisition closed on December 24, 2020.

Private Placement

In connection with the Acquisition, we held on December 24, 2020, an initial closing on a private placement of our securities with certain accredited investors providing for the issuance and sale to such investors of units of our securities (the "2020 Private Placement"), with each unit comprised of (i) two (2) shares of our common stock, par value $0.001 per share (the "Common Stock") and (ii) one (1) common stock purchase warrant to purchase an additional share of Common Stock (the "Warrant"), at a per unit purchase price of $0.64. The Warrant is exercisable through December 28, 2023 at a per share exercise price of $0.64. At the initial closing of the 2020 Private Placement, we raised aggregate gross proceeds of $2,306,000, prior to payment of offering related expenses of $161,000.

Between January and April 10, 2021, we raised additional approximate gross proceeds to the Company from the 2020 Private Placement of $3,525,000.

Comparison of the Three and Nine Months Ended September 30, 2021 to the Three and Nine Months Ended September 30, 2020

	For the three- months period ended September 30		For the nine- months period ended September 30	
	2021	**2020**	**2021**	**2020**
	U.S dollars (in thousands)			
Research and development expenses	**374**	46	**869**	192
Marketing expenses	**61**	-	**824**	-
General and administrative expenses	**287**	34	**977**	145
Total operating expenses	**722**	80	**2,670**	337
Financing expenses, net	**8**	9	**26**	11
Loss for the period	**730**	89	**2,696**	348

Revenues. We have not recorded any revenues to date.

Research and Development Expenses, Research and development expenses increased from $46,000 and $192,000 for the three and nine months ended September 30, 2020, respectively, to $374,000 and $869,000, respectively, for the corresponding periods in 2021. The increase in each of the three and nine months periods resulted primarily from the recruitment of employees, increased use of third party contractors for further research and development activities and the recording of non-cash expenses resulting stock based compensation to employees and service providers awarded in June 2021.

Marketing Expenses -During the nine months ended September 2021 we started to expend efforts to develop the marketing strategy for *PressureSafe*. In connection therewith, we recorded $61,000 and $824,000 for the three and nine months ended September 2021, respectively, which includes non-cash expenses attributable to stock based compensation to employees and service providers awarded in June 2021.

General and Administrative Expenses. General and administrative expenses increased from $34,000 and $145,000 for the three and nine months ended September 30, 2020, respectively, to $287,000 and $977,000 for the corresponding periods in 2021. The increase is primarily due to the increased resulted primarily from recruitment of new employees, patent registration in the U.S. accounting/audit related expenses and the recording of non-cash expenses due to stock based compensation to employees and service providers awarded in June 2021.

Loss. Loss for the three months and nine months ended September 30, 2021 was $730,000 and $2,696,000, respectively, and is primarily attributable to research and development, marketing activities, general and administrative expenses and the recording of non-cash expenses attributable to stock based compensation to employees and service providers awarded in June 2021.

Liquidity and Capital Resources

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.

As of September 30, 2021, we had a total of $3,550,000 in cash resources and approximately $408,000 of liabilities, consisting of $238,000 of current liabilities from operations. ,

We have experienced operating losses since its inception and had a total accumulated deficit of $4,176,000 as of September 30, 2021. We expect to incur additional costs and require additional capital. We have incurred losses in nearly every year since inception and in the nine months ended September 30, 2021. These losses have resulted in significant cash used in operations. During the nine months ended September 30, 2020 and 2021, our cash used in operations was approximately $279,000, and $1,660,000, respectively. We need to continue and intensify our research and development efforts for our product candidates (which are in various stages of development), strengthen our patent portfolio, establish operations processes and pursue FDA clearance and international regulatory approvals. As we continue to conduct these activities, we expect the cash needed to fund operations to increase significantly over the next several years.

At the initial closing of the 2020 Private Placement, we entered into a securities purchase agreement with certain accredited investors providing for the issuance and sale to such investors of an aggregate of 7,206,250 shares of our Common Stock and warrants for an additional 3,603,125 shares of our Common Stock, exercisable through December 28, 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 $2.14 million. Between January and April 2021, we raised an additional $3,525,000 in gross proceeds from the 2020 Private Placement.

Even after giving effect to the proceeds of the 2020 Private Placement, we will need to obtain additional funding in order to pursue our business plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We expect that our existing cash and cash equivalents will enable us to fund our operations and capital expenditure requirements 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 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 September 30,. 2021, 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 September 30, 2021, 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. 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 are exploring appropriate remediation options to address the identified material weaknesses.

Changes in Internal Control Over Financial Reporting

Except for the material weakness, during the quarter ended September 30, 2021, 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 Registration Statement on Form S-1, as filed with the SEC on October 28, 2021, 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 such registration statement.

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:

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/ Rom Eliaz*
Rom Eliaz
Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2021

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

Date: November 15, 2021

EXHIBIT 31.1

I, Rom Eliaz Soffer, 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/ Rom Eliaz*
Rom Eliaz, Chief Executive Officer
(Principal Executive Officer)

Date: November 15, 2021

EXHIBIT 31.2

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 15, 2021

EXHIBIT 32.1

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 September 30, 2021 (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/ Rom Eliaz

Rom Eliaz, Chief Executive Officer
(Principal Executive Officer)

Dated: November 15, 2021

EXHIBIT 32.2

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 September 30, 2021 (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 15, 2021