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

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Interim Unaudited Condensed Consolidated Balance Sheets

	September 30 2022	December 31 2021
	U.S dollars (in thousands)	
Assets		
Current assets		
Cash and cash equivalents	**3,786**	2,815
Accounts receivable	**83**	67
Total current assets	**3,869**	2,882
Non- current assets		
Long term restricted deposit	**11**	30
Right of use asset	**173**	-
Property and equipment, net	**70**	31
Total non-current assets	**254**	61
Total assets	**4,123**	2,943
Liabilities and stockholders' equity		
Current liabilities		
Trade and other payables	**328**	395
Non-current liabilities		
Long term lease liability	**58**	-
Stockholders' loans	**159**	177
Total non-current liabilities	**217**	177
Total liabilities	**545**	572
Stockholders' Equity		
Common stock, par value $0.001 per share, 250,000,000, shares authorized. 68,720,970 and 64,601,649 shares issued as of September 30, 2022, and December 31, 2021 respectively.	**68**	64
Additional paid-in capital	**11,350**	7,503
Accumulated deficit	**(7,840)**	(5,196)
Total stockholders' equity	**3,578**	2,371
Total liabilities and stockholders' equity	**4,123**	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 September 30		For the nine-months period ended September 30	
	2022	2021	2022	2021
	U.S dollars (in thousands)			
Research and development expenses	**468**	374	**1,357**	869
Marketing expenses	**24**	61	**205**	824
General and administrative expenses	**384**	287	**1,138**	977
Total operating loss	**876**	722	**2,700**	2,670
Financial expenses (income), net	(20)	8	**(56)**	26
Loss for the period	**856**	730	**2,644**	2,696
Basic and dilutive loss per common stock (in dollars)	**(0.01)**	(0.01)	**(0.04)**	(0.04)
Weighted average number of ordinary shares	**68,720,970**	**64,601,649**	**67,186,877**	**62,613,802**

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

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the nine-month period ended September 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	**4,119,321**	**4**	**3,621**	-	**3,625**
Stock-based compensation	-	-	**226**	-	**226**
Loss for the period	-	-	-	**(2,644)**	**(2,644)**
Balance as of September 30, 2022	**68,720,970**	**68**	**11,350**	**(7,840)**	**3,578**

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the nine-month 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

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

Interim Unaudited Condensed Consolidated Statements of Changes in Stockholders' Equity

	Common Stock		Additional paid-in Capital	Accumulated deficit	Total Stockholders' equity
	Number of Shares	Amount			
		U.S dollars (in thousands)			
For the three-month period ended September 30, 2022					

Balance as of July 1, 2022	**68,238,013**	**68**	**10,801**	**(6,984)**	**3,885**
Private placement of common stock and warrants, net	**482,957**	*	**425**		**425**
Stock-based compensation	-	-	**124**	-	**124**
Loss for the period	-	-	-	**(856)**	**(856)**
Balance as of September 30, 2022	**68,720,970**	**68**	**11,350**	**(7,840)**	**3,578**

(*)Represents an amount less than US$ 1 thousand

	Common Stock		Additional		Total
	Number of Shares	Amount	paid-in Capital	Accumulated deficit	Stockholders' equity
			U.S dollars (in thousands)		
For the three-month 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**

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 2022	September 30 2021
	U.S dollars (in thousands)	
Cash flows from operating activities		
Loss for the period	**(2,644)**	(2,696)
Adjustments to reconcile loss for the period to net cash used in operating activities:		
Stock based compensation	**226**	1,161
Depreciation	**10**	3
Accrued financial expenses (income)	**(18)**	3
Decrease in accounts receivable	**(16)**	109
Decrease in trade and other payables	**(154)**	(240)
Net cash used in operating activities	**(2,596)**	(1,660)
Cash flows from investing activities		
Purchase of property and equipment	**(48)**	(22)
Investment in restricted deposit	**(9)**	(12)
Net cash used in investing activities	**(57)**	(34)
Cash flows from financing activities		
Proceeds from private placement of common stock and warrants, net (see also note 1.B)	**3,625**	3,377
Net cash provided by financing activities	**3,625**	3,377
Effect of exchange rate changes on cash and cash equivalents	**(1)**	1
Net increase in cash and cash equivalents	**971**	1,684
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	**3,786**	3,550

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 optimizing the delivery of the targeted medical services and, as a result, improving the efficacy and safety of administered treatments.

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 nine months ended September 30, 2022, the Company incurred losses of $2,644 thousand and had a negative cash flow from operating activities of $2,596 thousand. The accumulated deficit as of September 30, 2022 is $7,840 thousand.

Management's plans regarding these matters include continued development and marketing of its products, as well as seeking additional financing arrangements. In April 2022, the Company raised $3,200 thousand from the private placement, in addition, During July 2022 the Company entered into Subscription Agreements with four Investors under the 2022 Offering on the same terms and conditions specified above where the Company issued 482,957 shares of its common stock at a per share price of $0.88 and warrants to purchase up to an additional482,957 shares of common stock at a per share exercise price of $1.10. The Company received aggregate gross proceeds of $425,000.

The Company Managements believes that its current cash resources are sufficient for its operations for 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.

Notes to the Interim Unaudited Condensed Consolidated Financial Statements

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 nine-months period ended September 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, except 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.

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.

Note 3 - Significant Accounting Policies (cont'd)

- 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 September 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 are 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 betweenthree to ten years from the vesting date. The grant was approved following the adoption of the 2020 incentive stock plan (hereinafter the "Plan") by the Company on December 23, 2020 and the adoption of the sub plan (the "Israeli appendix") on April 29, 2021.

Note 4 – Stock options plan (cont'd)

The Company recorded in the statement of operations a non-cash expense of $226 thousands during the nine-month period ended September 30, 2022.

The stock-based compensation expenses for the nine-month period ended September 30, 2022 were recognized in the statements of operations as follows; $65 thousands were recorded as research and development expenses, and $161 thousands were recorded as general and administrative expenses ($1,161 thousands were recognized for the nine-month period ended September 30, 2021).

The stock-based compensation expenses for the three-month period ended September 30, 2022 were recognized in the statements of operations as follows; $18 thousands were recorded as research and development expenses, and $106 thousands were recorded as general and administrative expenses ($94 thousands were recognized for the three-month period ended September 30, 2021).

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 September 30, 2022, using the Black- Scholes-Merton option-pricing model and the weighted-average assumptions used for such grants:

	For the nine months ended September 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%

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

On October 7, 2022, IR. Med, Ltd., our wholly owned subsidiary and PI Prevention Care LLC, a Delaware limited liability company (the "Distributor") entered into an exclusive Distribution and License Agreement (the "Distribution Agreement") pursuant to which the Distributor received exclusive royalty bearing rights to promote, market and sell solely in the United States the Company's proprietary patent protected *PressureSafe* monitoring device that is being developed to support early detection of pressure injuries (PI) to the skin and underlying tissue and related materials (hereinafter the "PressureSafe Solution"). The PressureSafe device is currently in advanced development and the Company expects to have a market ready device in 2023, subject to FDA approval.

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.

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*. In August 2022, IR Med. Ltd., entered into an agreement with a Israeli boutique industrial design company specializing in the design of medical devices and diagnostic products servicing a broad array of companies, including large multinational companies, for the design of the ***PressureSafe*** device in its advanced configuration, which incorporates preliminary results from a usability study currently being performed in Israel, including feedback from healthcare professionals.

Recent Developments

(i) During July 2022, we entered into Subscription Agreements with four Investors pursuant to which we agreed to issue and sell, in a private placement, 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, in

consideration of which we received aggregate gross proceeds of $425,000.

(ii) On October 7, 2022, IR. Med, Ltd. and PI Prevention Care LLC, a Delaware limited liability company (the "Distributor") entered into an exclusive Distribution and License Agreement (the "Distribution Agreement") pursuant to which the Distributor received exclusive royalty bearing rights to promote, market and sell solely in the United States our *PressureSafe* monitoring device (hereinafter the "*PressureSafe* Solution").

The Distributor is a recently formed Delaware entity comprised of persons and other entities including Company shareholders, who are active in the markets relating to senior care facilities, hospitals, home care centers, hospital equipment distributors, among others, throughout the United States and who are familiar with and have wide experience in addressing and responding to the needs of these medical care organizations.

Under the Distribution Agreement, the Distributor is solely responsible for the distribution, marketing and sales of the PressureSafe Solution and its accompanying components (hereafter collectively, the "Products") and agreed undertake all commercially reasonable efforts to establish t dihe necessary distribution and sales network for the Products by not later than the date on which the Company shall have received all regulatory and other clearance required to launch the commercialization of the *PressureSafe* Solution (such Date being the "Commercial Launch Date"). Prior to the Commercial Launch Date, the Distributor is to invest such resources as is reasonable such that upon the occurrence of the Commercial Launch Date there will be a commercially reasonable distribution network in place for the immediate marketing of the Product.

The Distribution Agreement provides for the payment of annual licensing fees. The Distribution Agreement also specifies the prices of each component of the Products payable to the Company and also provides for minimum annual purchase requirements of Product components in order to maintain exclusivity. If for whatever reason the Distributor does not comply with the minimum purchase requirements in any year, the Distributor can continue to have a non-exclusive license and distribution rights in the United States if the Distributor pays the annual license fee.

Subject to the compliance by the Distributor of its obligation under the Distribution Agreement, including the purchase by the Distributor of minimum annual purchase requirements of the components of the Products, the Distribution Agreement continues in effect for a term of thirteen years following the Commercial Launch Date. At the end of the initial three and eight year period, the parties are to enter into good faith negotiations as to the pricing of the Products and the minimum purchase quantities for the subsequent period. The Distributor also agreed to not distribute any products that compete with the Products.

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.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2022 to the Three and Nine Months Ended September 30, 2021

	For the three months ended September 30		For the nine months ended September 30	
	2022	**2021**	**2022**	**2021**
	U.S dollars (in thousands)			
Research and development expenses	**468**	374	**1,357**	869
Marketing expenses	**24**	61	**205**	824
General and administrative expenses	**384**	287	**1,138**	977
Total operating expenses	**876**	722	**2,700**	2,670
Financial expenses (income), net	**(20)**	8	**(56)**	26
Loss for the period	**856**	730	**2,644**	2,696

Revenues. During the three-month and nine-month period ended September 30, 2022, and 2021, we did not recorded any revenues from operation.

Research and Development Expenses- Research and development expenses consist of salaries and related expenses, consulting fees, service providers', costs, and overhead expenses. Research and development expenses increased from $ 374,000 and $869,000 for the three and nine months ended September 30, 2021, respectively, compared to $468,000 and $1,357,000 respectively, for the corresponding periods in 2022. The Company's research and development program began to intensify in the third quarter of 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 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 $61,000 and $824,000 for the three and nine months ended September 30, 2021, respectively, to $24,000 and $205,000 respectively, for the corresponding periods in 2022. The decrease in marketing expenses resulted primarily from reduced 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 increased from $287,000 and $977,000 for the three and nine months ended September 30, 2021, respectively, to $384,000 and $1,138,000 for the corresponding periods in 2022. The increase in general and administrative expenses resulted primarily from increased expenses related to service providers and salaries and related expenses to support our general and administrative operation, increasein salaries and related expenses. With respect to the nine month periods, these expenses were partially offset by the lower non-cash expenses in 2022 period attributable to the options awards which were made in June 2021 to employees and service providers.

Loss. Loss for the three and nine months ended September 30, 2022 was $856,000 and $2,644,000, respectively, as compared to the three and nine month period ended September 30, 2021 of 730,000 and $2,696,000. The increase in net loss is and is primarily attributable to research and development and general and administrative expenses, partially offset by the lower non-cash expenses recorded in the 2022 periods attributable to the options awards which were made in June 2021 to employees and service providers.

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 $5,830,000. Between April and July 2022, we raised an additional $3,625,000 from sales of our equity and equity linked securities.

As of September 30, 2022, we had a total of $3,786,000 in cash resources and approximately $545,000 of liabilities, consisting of $328,000 of current liabilities from operations.

The following table provides a summary of operating, investing, and financing cash flows for the nine months ended September 30, 2022 compare to the corresponding period in 2021 (in thousands):

	For the nine months ended September 30	
	2022	**2021**
	U.S dollars (in thousands)	
Net cash used in operating expenses	**(2,596)**	(1,660)
Net cash used in investment activities	**(57)**	(34)
Net cash provided by financing activities	**3,625**	3,377

We have experienced operating losses since inception and had a total accumulated deficit of $7,840,000 as of September 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 nine months ended September 30, 2022. These losses have resulted in significant cash used in operations. During the nine months ended September 30, 2022, our cash used in operations was approximately $2,596,000, compared to $1,660,000 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), complete product design efforts and strengthen our patent portfolio, 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, through July 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. 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 our 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 equals or exceed 75,000 shares, in each case for the forty (40) consecutive trading days. The aggregate gross proceeds from the 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 provide assurance that future funding will be available to us on acceptable terms, or at all. Due to often volatile nature of the financial markets, equity and debt financing may be difficult to obtain.

We may seek to raise any necessary additional capital through a combination of private or public equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing and distribution arrangements. To the extent that we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights, future revenue streams, or product candidates or to grant licenses on terms that may not be favorable to us. If we raise additional capital through private or public equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

A smaller reporting company, as defined by § 229.10(f)(1), is not required to provide the information required by this Item

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 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 September 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

Except as described above, during the quarter ended September 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

The Company is not currently involved in any legal proceedings. However, from time to time we may become involved in various legal proceedings that arise in the ordinary course of business, including actions related to our intellectual property. Although the outcomes of these legal proceedings cannot be predicted with certainty, we are currently not aware of any such legal proceedings that arise in the ordinary course of business, including actions related to our intellectual property. Although the outcomes of these legal proceedings cannot be predicted with certainty, we are currently not aware of any such legal proceedings or claims that we believe, either individually or in the

aggregate, will have a material adverse effect on our business, financial condition, or results of operations.

ITEM 1A. RISK FACTORS

An investment in the Company's Common Stock involves a number of very significant risks. You should carefully consider the risk factors included in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 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, 2022.

ITEM 2. UNREGISTERED SALES OF SECURITIES AND USE OF PROCEEDS

N/A

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

N/A

ITEM 5. OTHER INFORMATION:

On November 14, .2022, our board of directors awarded to Aharon Binur, our Chief Development Officer, options under the Company's employee stock option plan for 300,000 shares of the Company's common stock at a per share price of $0.58, to vest over three years in equal quarterly instalments of 25,000 option shares at the end of each quarter beginning on the quarter ending December 31, 2022, provided that Mr. Binur is then in our service.

ITEM 6. EXHIBITS

Exhibit Index:

10.1	Distribution and License Agreement dated as of October 7, 2022 entered into by IR. Med, Ltd. and PI Prevention Care LLC ***
31.1	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
31.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
32.1	Certification of Chief Executive Officer (Principal Executive Officer), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer (Principal Financial and Accounting Officer) pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

*** Portion of the Exhibit have been omitted.

SIGNATURES

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

IR-Med, Inc.
(Registrant)

By:	*/s/ Moshe Gerber* Moshe Gerber Chief Executive Officer (Principal Executive Officer)	By:	*/s/ Sharon* Levkoviz Sharon Levkoviz Chief Financial Officer (Principal Financial and Accounting Officer)
Date:	November 14, 2022	Date:	November 14, 2022

Exhibit 10.1

CERTAIN INFORMATION HAS BEEN EXCLUDED FOM THE EXHIBIT AS SUCH INFORMATION IS NOT MATERIAL AND WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED ([***]).

DISTRIBUTION AND LICENSE AGREEMENT

This Distribution and License Agreement (this "Agreement") is made and entered into as of October 7, 2022 (the "Effective Date") between**I.R Med Ltd.**, a company formed under the laws of the State of Israel, with an address at Z.H.R Industrial Zone, Rosh Pina Israel ("IR-Med" or the "Company"), and PI Prevention Care LLC, a Delaware limited liability company ("Distributor").

RECITALS

WHEREAS, Distributor will be comprised of persons with access to or who represent senior/elder care facilities and/or hospitals or other medical centers throughout the United States (collectively, the "Medical Care Centers") and who are familiar with and have wide experience in addressing and responding to the needs of these Medical Care Centers,; and

WHEREAS, IR-Med is engaged in the development, manufacturing, sale and support of a proprietary patent protected solution for the early detection of pressure injuries (PI) to the skin and underlying tissue primarily caused by prolonged pressure associated with bed confinement, which includes a handheld optical monitoring device that is being developed to detect such pressure injuries and interaction with an online cloud information system (hereinafter the "*PressureSafe* Solution"), which currently being developed and therefore not currently available on the market;

WHEREAS, Distributor represents that it has the experience, expertise, skill and financial ability to establish distribution networks in the United States for the marketing, sale and delivery of the *PressureSafe* Solution amongst the Medical Care Facilities once the *PressureSafe* Solution has obtained all regulatory authorization to be markets in the United States;

WHEREAS, Distributor further represents that it will invest at its cost and expense in establishing the necessary distribution and support networks for the commercialization of the *PressureSafe* Solution, in consideration of which the Company is agreeable to grant to the Distributor the distribution right and license as herein provided,

WHEREAS, in furtherance thereof, Distributor and IR-Med desire to enter into an agreement whereby Distributor will be the exclusive sales representative of the *PressureSafe* Solution throughout the United States, subject to the terms and milestones as set forth in this Agreement.

NOW THEREFORE, in consideration of the above recitals and in consideration of the mutual agreements and undertakings set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

AGREEMENT

1. Grant of Right. (i) Subject to the terms and conditions of this Agreement, IR-Med grants to Distributor, and Distributor hereby accepts, an exclusive right to promote, market and sell the *PressureSafe* Solution, including the associated Disposables and access to the Software modules, as those terms are defined in and as further specified in **Appendix A**, including any future product developed and marketed by the Company that is intended to be used in the diagnosis of pressure injuries on the skin surface (collectively, the "Products"), in the United States (the "Territory") during the term of this Agreement. The term *Products* shall include and refer to any upgraded or enhanced version of the *PressureSafe* Solution including, without limitation, any 'homecare' version that the Company may then market.

In connection with the above rights, IR-Med hereby grants to the Distributor an exclusive royalty bearing license, with the right to sublicense, to demonstrate the Software (as defined in **Appendix A**) solely for the purpose of promotion, marketing, sale and distribution of the Products. Such license shall be sub-licensable solely to permitted sub-distributors as set forth below.

With "exclusive" meaning that IR-Med will not sell in the Territory any of its Products during the term of this Agreement and Distributor will in turn not market and/or sell any competing products in the Territory. (ii) IR-Med and Distributor acknowledge and agree that in order for the Product's commercialization efforts to succeed, Distributor will be appointing through the continental United States sub-distributors with access to distribution networks to Medical Care Centers in their respective areas within the Territory. Accordingly, Distributor may, subject to the terms hereof, appoint sub-distributors to promote and sell the Products on behalf of Distributor within the Territory, provided, that the Company shall have been given written notice of such impending appointment and then the Company shall have fourteen(14) business days to reject such appointment based on reasonable commercial grounds. Distributor will obligate in writing its sub-distributors to adhere to the terms applicable to Distributor and will establish reasonable monitoring processes and safeguards to ensure compliance. Nonetheless, Distributor shall be liable for any breach of such sub-distributor any applicable rule and regulation relating to the marketing and distribution of the Products.

At its sole discretion, IR-MED is entitled to appoint additional sub-distributors who will work under the Distributor, with the prior coordination and approval of the Distributor, as to the sub-distributor and related conditions (such as the sub-distributor's territory and the commission). The Distributor will work in a good faith with IR-MED to add the additional sub-distributors.

(ii) Termination of Exclusivity. (A) Notwithstanding the foregoing, in the event that for whatever reason the Distributor does not satisfy the annual minimum purchase requirements of the Products set forth in **Appendix B**, then so long as the Distributor shall remit to IR-Med the annual licensing fee then due as set forth in**Appendix A** and the Distributor is in compliance with the other provisions of this Agreement, then except as herein provided, upon written notice provided by IR-Med to the Distributor (the "Exclusivity Termination Notice") the exclusivity provision in this Agreement shall without any further action on the part of any of the parties immediately terminate and be of no further force and effect and the rights to the Distributor hereunder shall be deemed to be on a non-exclusive basis and the Agreement shall be deemed to have been automatically adjusted accordingly; ***provided, that***, with respect any customer (end user) or subdistributor of the Distributor, the exclusivity provision of this Agreement shall continue in full force who purchased from the Distributor Products at the invoiced price in the aggregate amount of at least $**[***]**during the (12) months preceding the delivery of the Exclusivity Termination Notice or $**[***]** in the twenty-four month period preceding the delivery of the Exclusivity Termination Notice and, with respect to a customer (end user), who continues to purchase from the Distributor Products at an total invoiced price in the aggregate amount of at least $**[***]**during each 12 month period and, with respect to a subdistributor of a Distributor, the subdistributor continues to purchase from the Distributor Products during each 12 month period in an amount above the immediately preceding year by a factor of **[***]**% (in each such case, the "Distributor's Exclusive Customer/Sub-distributor"), ***provided, further, that***, the aggregate amount of the Distributor's purchased amount from the Company during any 12 month period shall always exceed by a factor of **[***]**% such amount in the previous 12 months in order to maintain the exclusivity with respect to all customers and subdistributors, the failure of which, for whatever reason, shall entitle the Company to terminate the Agreement

Notwithstanding the foregoing, following the delivery of the Exclusivity Termination Notice until such time as IR-Med shall have entered into a distribution or similar agreement with a third party respecting *exclusive* distribution rights in the Territory or any part thereof (such agreement being the "Subsequent Exclusive Distribution Agreement"), the Distributor shall have exclusive distribution rights with respect to any *new* customer (end user) or sub-distributor to whom the Distributor shall have sold Products at the invoiced price in the aggregate amount of at least $**[***]**during the *earlier* of (i) the preceding 12 months or (ii) the date on which the subsequent exclusive agreement is entered into, and such exclusivity shall continue, with respect to such customer (end user) or sub-distributor so long as such customer or sub-distributor shall continue to purchase from the Distributor Products at the invoiced price in the aggregate amount of $**[***]**during each 12 month period and, with respect to a subdistributor of the Distributor and, with respect to a customer (end user), who continues to purchase from the Distributor Products at an total invoiced price in the aggregate amount of at least $**[***]**during each 12 month period and, with respect to a subdistributor of a Distributor, the subdistributor continues to purchase from the Distributor Products during each 12 month period in an amount above the immediately preceding year by a factor of **[***]**% (in each such case, the "Distributor's Exclusive Customer/Sub-distributor"), ***provided, further, that***, the aggregate amount of the Distributor's purchased amount from the Company during any 12 month period shall always exceed by a factor of **[***]**% such amount in the previous 12 months in order to maintain the exclusivity with respect to all customers and subdistributors, the failure of which, for whatever reason, shall entitle the Company to terminate the Agreement.

To the extent that in the Subsequent Exclusive Distribution Agreement there are terms or conditions more favorable to the distributor thereunder than those terms and provisions applicable to the Distributor hereunder (such terms being the "Favorable terms") , then without any further action on the part of the Company or the Distributor the terms shall have the benefit of the Favorable Terms with respect to the Distributor's Exclusive Customer/Sub-distributors.

(B) The Company and the Distributor agree that the marketing and distribution of Products to licensed hospitals in the Territory (in each case, a "Hospital" and collectively, the "Hospitals") is required (the "Company Hospital Policy"). In case of any barrier in selling to the Hospitals, the Company and the Distributor will try to work together to find a solution.

Accordingly, commencing as of the second year anniversary of the Reimbursement Approval (as defined in **Appendix B** below) and so long as the Company shall then have in effect a Company Hospital Policy, the Distributor shall sell to one or more Hospitals, an amount equal to, in each year, at least **[***]**% of the minimum amount of *PressureSafe* devices and Disposables that the Distributor is required to purchase from the Company during such year as provided in **Appendix B**. If for whatever reason, the Distributor fails to comply with this provision in respect of any 12 month period, then at the Company's option and upon delivery to the Distributor of the Exclusivity Termination Notice, the exclusivity provisions with respect to Hospitals in the Territory shall be terminated, effective upon the date specified in the Exclusivity Termination Notice; provided, that, any such termination of exclusivity by the Company shall not affect the continued exclusivity that the Distributor shall have with respect to Nursery-Homes and Homecare in the Territory so long as the Distributor complies with the minimum amount of *PressureSafe* devices and Disposables that the Distributor is required to purchase from the Company during such year as provided in **Appendix B.**

2. Sale of Product to Distributor. IR-Med will sell to the Distributor the Products and license the Software component on the terms and conditions specified in **Appendix A** and **Appendix B**, which terms and conditions may be updated from time to time as deemed relevant by the Parties. Distributor may purchase and shall take delivery of ordered Products from IR-Med, and IR-Med will be responsible to design, develop, and manufacture the Products and will use reasonable efforts to deliver to Distributor the volumes and versions of Products ordered by Distributor, for resale on an exclusive basis in the Territory under IR-Med's brand name. All Product purchases hereunder shall be accompanied by a legally binding purchase order (the "Product Purchase Order") in form and substance acceptable to IR-Med.

   So long as this Agreement is in effect, IR-Med shall notify Distributor of any leads or inquiries that it receives from parties expressing interest in purchasing or having a demonstration of the Products, in accordance with a process to be mutually agreed by the Parties.

3. Undertakings of IR-Med and Distributor.

   3.1. IR-Med will be responsible for all aspects of the Products other than out of pocket marketing expenses and sales, including, without limitation, the design, manufacture, assembly, and delivery of Products to Distributor.

   IR-Med will provide Distributor, at no cost to Distributor, all technical assistance, and training materials as may be reasonably requested to perform its obligations under this Agreement.

   3.2. IR-Med will, at IR-Med's expense, provide, prepare and deliver to Distributor existing supportive promotional and marketing materials pertaining to the Products and, , shall prepare and deliver additional promotional and marketing materials as may be reasonably requested by Distributor for distribution to prospective purchasers of the Products. All product delivery terms will be on terms agreeable to the parties.

   3.3. Prior to any activities being undertaken hereunder, the appropriate personnel of IR-Med will, at the Company's expense, travel to the U.S. and train Distributor personnel in all aspects of the Products, as deemed necessary by the Company.

   3.4. The Distributor shall be solely responsible for the distribution, marketing and sales of the Products in the Territory and shall undertake all commercially reasonable efforts to establish by not later than the Commercial Launch Date (as defined below) a commercially reasonable distribution and sales network for the Products. In furtherance thereof, within 90 days following the execution of this Agreement, Distributor shall present a reasonably detailed written work plan for the initial three years to include specific plans to satisfy milestones and responsibilities as set forth on **Appendix** B (each a "Milestone" and collectively, the "Milestones"). The Milestone are divided into time periods in which the Distributor's undertakings and commitments are expressly set forth covering the following time periods: (i) immediately following execution of this Agreement, (ii) the date on which the Company shall advise the Distributor that it has received all regulatory and other clearance required to launch the commercialization of the Product (the "Commercial Launch Date") , (iii) the date on which the Company shall advise the Distributor that the Product has been cleared for insurance reimbursement by Medicare and Medicaid (the "Insurance Reimbursement Date"), and (iv) the date on which the Company shall advise the Distributor that the U.S. National Pressure Injury Advisory Panel (NPIAP) has updated its guidelines to recommend the use of technologies and devices such as the Product to be used as a decision support tool for PI checking (the "NPIAP Guidelines Date"). The Distributor acknowledges and agrees that these Milestones are critical to the success of the Product commercialization efforts in the Territory and Distributor's failure to satisfy in a timely manner any Milestone shall authorize the Company to terminate the Agreement as herein provided.

   The Milestones may be modified from time to time as the circumstances warrant subject to a mutually agreeable written amendment to the work plan executed by both the Distributor and the Company.

   3.5. Distributor shall provide IR-Med with a quarterly report, due within 10 days of the end of each quarter, which will include at a minimum the following:

      (i) the identity, address and other identifying and pertinent details of each customer or prospective customer approached with respect to the Products;

      (ii) the amounts purchased by such customer during the quarter;

      (iii) the price per each component of the Product charged by the Distributor and paid by such customer;

(iv) complaints received from customers relating to the Products or its functionality described in reasonable detail; and

(v) the progress made by Distributor in meeting the next scheduled Milestone;

provided, that, notwithstanding the foregoing, any change to the price per unit charged by the Distributor to the customer with respect to each component of the Products shall be immediately notified in writing to IR-Med by not later than the second business day following the implementation of such price increase.

3.6. IR-Med agrees that so long as this Agreement is in effect, IR-Med will not initiate any direct communication with any such customer and will not, directly or indirectly, attempt to initiate contact or otherwise circumvent Distributor in regard to such customer with respect to the commercialization of the Productor any other product that IR-Med intends to distribute in the area of pressure injuries.

3.7. At all times Distributor shall maintain in inventory of sufficient Products to meet the reasonably foreseeable demand for the Products and Disposables. IR-Med will use commercially reasonable efforts to comply with and respond to all Product purchase orders submitted by Distributor or Distributor's sub-distributors. IR-Med and Distributor shall periodically establish minimum quotes of inventory so as to avoid any inventory shortfall. The terms relating to the submission of minimum purchase orders by the Distributor are specified in **Appendix C** hereof (the "Distributor Purchase Order Procedures").

3.8. Defective Products. Distributor shall process and return any defective Products to IR-Med for credit or replacement. Should the Product in question be defective and under Warranty as herein provided, then all expenses related to its return and replacement shall be borne by IR-MED. After the warranty period the Distributer shall be responsible for all such expenses.

3.9. Alteration of Products. Distributor shall not alter the Products or any Product packaging or labelling except with the prior written consent of IR-Med.

3.10. Forecasts. Distributor agrees to provide IR-Med with a non-binding twelve (12) month forecast indicating Distributors' projected purchase of Products for the Territory. Such forecast shall be updated by Distributor on a rolling quarterly basis for each succeeding twelve (12) month period, and each updated forecast must be received by IR-Med no later than thirty (30) days prior to the first day of the period to which it relates. Such forecasts by Distributor shall be used for the purposes of facilitating IR-Med and its suppliers' planning to meet production and delivery times for the Products, and shall not constitute binding commitments to purchase upon Distributor. Distributor will use its best efforts to notify IR-Med promptly of any changes in its forecast. The initial 12 month forecast shall be submitted by the Distributor within 90 days of the Effective Date.

3.11. Appointment of Sub-Distributors. As noted, IR-Med and the Distributor acknowledge and agree that the appointment by Distributors of sub-distributors within the Territory is integral to the success of the commercialization efforts that is the subject of this Agreement. Accordingly, the parties agree to the following

(i) Prior to appointment of a sub-distributor, the Distributor shall identify in writing to IR-Med the identity and other relevant details as to such proposed sub-distributor. This information will be used by IR-Med solely for the purposes of monitoring the distribution of the Products within the Territory.

(ii) IR-Med agrees that so long as this Agreement is in effect, will not initiate any direct communication with any such sub-distributor and will not, directly or indirectly, attempt to initiate contact or otherwise circumvent Distributor in regards to such sub-distributor with respect to the commercialization of the Product or any other product that IR-Med intends to distribute.

3.12. Notice of Intellectual Property Infringement. Distributor shall promptly notify IR-Med in writing of any patent, copyright infringement or unauthorized use of IR-Med's trade secrets in the Territory of which Distributor has become aware. IR-Med reserves the right in its sole discretion to institute any proceedings against such third-party infringers in its name and on its behalf and on behalf of the Distributor. Distributor shall cooperate fully with IR-Med in any legal action taken by IR-Med against such third parties, provided that IR-Med shall pay all expenses of such action and all damages relating to damage suffered by IR-Med which may be awarded upon in settlement of such action shall accrue to IR-Med. At the request of the Distributor, IR-Med and the Distributor shall enter into good faith negotiations relating to portion to the damages awarded to IR-Med, if any, which should be remitted to the Distributor to mitigate the actual damages, of any, that the Distributor may have incurred as a result of such infringement.

3.13. Compliance with Laws of the Territory. Upon knowledge, Distributor will do its commercial reasonable efforts to inform IR-Med of any legal requirements in the Territory that may affect the use or distribution of the Products, marketing materials or Product packaging and labelling. In all circumstances, the Distributor shall comply with all pertinent regulations and law in the applicable jurisdiction in the Territory.

3.14. Insurance. At all times following the Commercial Launch Date, IR - Med will have in place one or more policies of product liability and other insurance in amounts typical and appropriate for the relevant industry. The Distributor shall implement one or more insurance policies covering the marketing and distribution of the Products and the Distributor shall be named as an additional beneficiary under any such policy or otherwise as necessary such that the Distributor shall be covered by such policy to the same extent and coverage as provided to the Company.

3.15. Adverse Reactions. In the event that either party receives any complaint regarding the Product, it shall notify the other party immediately after becoming aware of it. Distributor will make an assessment of each complaint it receives, provide IR-Med with these complaint assessments and will coordinate all follow-up and customer communication that it deems appropriate.

In the event that any customer of Distributor rejects or returns a Product to Distributor as a result of a Product performance problem, Distributor shall immediately so notify IR-Med and confirm in writing. If the reason for such performance problem is reasonably determined to be failure of the Product to meet its specifications, and the Product is still under Warranty then IR-Med will replace, at its sole expense, the non-conforming Product which Distributor elects to so replace. In such case, IR-Med will pay all shipping and handling costs of Distributor relating to the handling, replacement and return of the rejected Product. After the Warranty Period the Distributer shall be responsible for all such expenses.

3.16. Warranty. IR-MED warrants that each Product purchased will be free from material defects in workmanship and materials for a period of eighteen (18) months ("Warranty Period") from the date of its initial shipment to the Distributor. The Company's obligations under this warranty are limited to repair or replacement, at Company's option and election, of any warranted product. Repair or replacement of Products under this limited warranty does not extend the Warranty Period but shall be covered to the extent of the unexpired term of the applicable warranty period.

3.17 Composition of the Distributor. Mr. Shlomie Bierman shall be appointed to the board of directors or other governing body of the Distributor and shall have legal authority to bind the Company. Mr. Bierman shall execute the Agreement on behalf of the Distributor.

4. Steering Committee. Promptly following the Effective Date, the Parties shall establish a committee composed of two (2) representatives of each of IR-Med and Distributor, who may be re-designated from time to time upon notice to the other Party (the: Steering Committee"). The Steering Committee is established to oversee the Parties' performance under this Agreement consistent with the intent and scope of the Agreement, and resolve disputes arising from performance, consistent with such intent and scope, as set forth in the Appendices attached to this Agreement. The Steering Committee shall meet at least once per quarter (in person or via teleconference) during the Term of this Agreement.

5. Resale Prices. Distributor may offer the Products in the Territory at such prices as Distributor, in its sole discretion, shall determine. IR-Med shall be apprised in writing of all such prices.

6. Adoption of the Products. Distributor shall be solely responsible for marketing and distributing the Products to the Customers and to provide the support necessary to assist customers' adoption of the Product and Disposables and utilization of the Software. In particular, Distributor will develop at its own cost a clinical field organization for Customer training, education and system use with the goal of executing such adoption plan, maturing the Products value proposition and driving customer usage of Disposables. Initially, following the execution of this Agreement, the Distributor shall present to IR Med a written proposal to accomplish these objectives. Once additional Software modules are ready for commercial use, Distributor shall provide Company with a revised written proposal to market same.

7. Installation, Service, Warranty.

7.1. Distributor will install, warrant, service and support the Products (excluding repairs – those shall be performed by IR-Med), for its own account and at its risk and directly to the customers at Distributor's expense. As between the Parties, Distributor will have the sole right and responsibility for:

7.1.1. Managing customer acceptance,

7.1.2. Preventative and corrective maintenance, including corrective action requests,

7.1.3. Monitoring quality performance, and

7.1.4. Providing at least one training session of Product training for the Distributor's employees, consultant and sub-distributors per quarter.

7.1.5. **I**t is the sole responsibility of Distributor to provide customer service to persons or entities purchasing the Products. Distributor will bear full responsibility for all customer service, including without limitation, order processing, billing, fulfillment, shipment, collection and other customer service related tasks, and IR-Med will have no obligations whatsoever with respect thereto. Distributor will receive all emails from customers via a computer available to Distributor's customer service staff and generally respond to such emails within three (3) days from receipt. Distributor will receive all orders electronically and generally process all orders within three (3) days from receipt. Distributor will use commercially reasonable efforts to receive, process, fulfill and deliver all orders of Products and related services on a timely and professional basis. Distributor will bear all responsibility for compliance with federal, state and local laws. Payment for such services will be collected by Distributor directly from customers. IR-Med shall be allowed to audit the customer service provisions as needed. At all times, IR-Med shall continue to bear sole responsibility for the design and of the Product, including systems and product upgrades, all of which will be shared with the Distributor. Notwithstanding the foregoing, IR-Med shall be solely responsible for all matters relating to the digital storage and maintenance of the Software component of the Product.

7.1.6. Distributor shall set up service centers to implement the foregoing distribution related activities. All such service centers shall be managed and overseen by qualified Distributor's personnel who are acceptable to IR-Med (in IR-Med's sole discretion exercised on a commercially reasonable basis). IR-Med shall have discretion as to the makeup of these services centers and whether they are to be virtual or physically existing. Distributor acknowledges and agrees that the appropriate, timely and adequate response to customers' inquiries or service assistance is of paramount importance to IR-Med.

7.1.7. Maintaining Field Data: Distributor shall maintain a database of all the Products shipped to end customers with details per Device and Disposables, including, the end customer contact details, serial number of the Device, date shipped to end customer. In case of a production defect , the Distributor should be able to collect Devices from end customers according to a list of serial numbers provided by the Company.

8. Audit.

8.1. Distributor shall keep accurate books and records of Distributor's net sales of the Products, and shall not destroy such books and records for a period of one (1) year following the termination of this Agreement.

8.2. IR-Med shall have the right at its own expense, after thirty (30) days advance written notice to Distributor, to perform or have performed an audit of Distributor's books and records related to this Agreement. IR-Med or its appointee shall have access to Distributor's books and records during reasonable business hours for the sole purposes of auditing the reports (and supporting books and records) and verifying the amounts payable as provided for in this Agreement. Distributor shall promptly pay to IR-Med all underpayments disclosed by an audit. Although the fees and expenses of such inspection/audit shall initially be borne by IR-Med, if an underpayment of amounts due to IR-Med under this Agreement of more than five (5%) of the aggregate amount due to IR-Med hereunder is discovered, then such fees and expenses shall be borne by Distributor, and Distributor shall promptly pay IR-Med any such delinquent amounts with interest thereon at the prime rate reported by the Bank of America, computed from the date such amounts were due until the date Distributor pays such royalty amounts.

9. Intellectual Property.

9.1. Intellectual Property Rights. Except as provided herein, IR-Med shall retain sole ownership of, and all rights to, any intellectual property of any kind underlying the Products, the Disposables and the Software and any suggestions, ideas, enhancement requests, feedback, recommendations or other information provided by Distributor or any other party (collectively, the "Feedback"). Without limiting the generality of the foregoing, Distributor agrees that its provision of Feedback does not give it any intellectual property or any other right, title, or interest in or to software, inventions, or other assets created by IR Med, even if such Feedback leads IR Med to create the software, invention, or other asset.

9.2. Distributor agrees not to decompile, dis-assemble, or in any other way reverse engineer computer hardware and/or software incorporated in the Product. The Distributor shall establish and enforce commercially reasonable safeguards to prevent such activities by any of its employees, consultants and/or sub-distributors.

10. Confidential Information.

10.1. Any non-public, proprietary information disclosed by one party to the other shall constitute confidential information ("Confidential Information"). Neither party will disclose or disseminate either any of the other party's Confidential Information without the prior written consent of the other party. Each party acknowledges that any unauthorized use, misappropriation or disclosure of the other party's Confidential Information will cause irreparable harm and will entitle such other party to injunctive relief, as well as any other available remedy at law or in equity.

10.2. Confidential Information shall not include any information which is (a) in the public domain or becomes public knowledge, through no fault or breach by the recipient; (b) obtained from a third party lawfully in possession of such information, other than by breach of an obligation of confidentiality; (c) previously known or independently developed by the recipient; (d) released for disclosure by either party; or (e) required by court order, law or regulation to be disclosed, but only to the extent and for the purposes of the required disclosure.

The receiving party agrees that it will (i) hold in confidence and not disclose to any third-party, other than its representatives, any Confidential Information of the disclosing party; (ii) protect such Confidential Information with at least the same degree of care that receiving party uses to protect its own Confidential Information, but in no case, less than a reasonable degree of care; (iii) use the Disclosing Party's Confidential Information for no purpose other than the purposes specified in this Agreement; (iv) limit access to the disclosing party's Confidential Information to its representatives reasonably having a need to know such Confidential Information; (v) promptly notify the disclosing party upon discovery of any loss or unauthorized disclosure of the disclosing party's Confidential Information.

11. Regulatory Compliance

11.1 Both Parties will at all times comply with all laws, rules, regulations and ordinances applicable to the Agreement, including but not limited to all applicable anti trust laws, fair labor, equal opportunity and environmental compliance laws, and import and export rules, regulations and ordinances. Either Party will furnish to the other Party any information required to enable it to comply with such laws, rules, and regulations. If the Products and/or Services are sold by Distributor under U.S. federal contract or subcontract, all applicable procurement regulations required by federal statute or regulation to be inserted in contracts or subcontracts are hereby incorporated by reference.

11.2. Personal data. If a Party receives or has access to personal data, as defined in any applicable personal data protection legislation or similar law or regulation ("Personal Data"), in the performance of this Agreement, then that Party will

a) not use or further disclose Personal Data other than as permitted by this Agreement or required by law;
b) use appropriate safeguards to prevent the use or disclosure of the Personal Data other than as permitted by this Agreement, and
c) implement administrative, physical, and technical safeguards that reasonably and appropriately protect the Personal Data against unauthorized or unlawful processing of the Personal Data.

To the extent that either Party uses an authorized subcontractor with access to the Personal Data, such Party will obtain subcontractor's written agreement to this provision. Both Parties will comply with the applicable data protection legislation and all further reasonable instructions provided by the other Party with regard to the processing and protection of the Personal Data. Either Party will use reasonable efforts to mitigate any harmful effect that is known to it of its use or disclosure of Personal Data in violation of the law or this Agreement. The Parties will, upon the termination of this Agreement, return to the other Party or securely destroy all records or documents containing the Personal Data. The Parties will remain bound by the provisions of this Section with respect to any Personal Data that remain in its possession.

Insofar images or other health related records that will be provided by a Party to the other Party under this Agreement contain Personal Data or references thereto, the first party will ensure that all such Personal Data and references are removed or made illegible or inaccessible prior to the disclosure to the receiving party. Where the Personal Data cannot be removed, or be made illegible or inaccessible, but it cannot be avoided to share this Personal Data with the other Party, the transferring Party warrants that it has obtained the explicit consent of the data subject concerned with regard to the disclosure of the Personal Data or reference thereto to the other Party as well as the use of those Personal Data or references thereto by the other Party for business, research and marketing purpose

11.3 In connection with providing services hereunder, either Party may disclose to the other Party individually identifiable health information ("PHI") as defined in and subject to protection under the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated pursuant thereto ("HIPAA"). The customers include "Covered Entities," which are subject to HIPAA. This paragraph is to allow customers to comply with HIPAA. "PHI" and "ePHI" will mean Protected Health Information and Electronic Protected Health Information, respectively, as defined in 45 C.F.R. §160.103, limited to the information the other Party received from or created or received on behalf of a Party. The parties shall share information only to the extent permitted under HIPAA.

11.4 Distributor and IR Med agree that: (1) The receiving Party will not use or further disclose PHI other than as permitted by this Agreement or required by law; (2) the receiving Party will use appropriate safeguards to prevent the use or disclosure of the PHI other than as permitted by this Agreement, and will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of ePHI ("**Safeguards**"); (3) the receiving Party will report to the transferring Party: (a) any use or disclosure of the PHI not permitted by this Agreement or by law of which the receiving Party becomes aware; and (b) any Security Incident (as defined by law) of which the receiving Party becomes aware; (4) To the extent that the receiving Party uses one or more subcontractors or agents to provide services under this Agreement, and such subcontractors or agents receive or have access to the PHI, each such subcontractor or agent will: (a) enter into a written agreement with the receiving Party containing the same restrictions and conditions set forth in the business associate provisions of HIPAA that apply through the receiving Party; and (b) implement reasonable and appropriate Safeguards to protect ePHI; (5) the receiving Party agrees to make (a) its internal practices, books and records relating to the use and disclosure of PHI and (b) its policies, procedures and documentation required by the Security Rule relating to the Safeguards, available to the Secretary of the U.S. Department of Health and Human Services or his designee to the extent necessary to determine the receiving Party's compliance with HIPAA; (6) the receiving Party agrees to make available to the other Party (or at its direction to a Customer) the information in its possession required to provide an accounting of the receiving Party's disclosures of PHI as required by HIPAA (7) the receiving Party will use reasonable commercial efforts to mitigate any harmful effect that is known to the receiving Party of a use or disclosure of PHI by the receiving Party in violation of this Agreement; and (8) Upon the termination of this Agreement for any reason, the receiving Party will return to the transferring Party (or at its direction to a Customer) or destroy all PHI received from the transferring Party or a Customer that the receiving Party maintains in any form, recorded on any medium, or stored in any storage system, unless said information is no longer PHI or if the return or destruction is not feasible. Following termination of this Agreement, the receiving Party will remain bound by the provisions of this Paragraph with respect to any PHI that remains in its possession

12. Representations and Warranties and Undertaking of the Parties.

12.1. Representations and Warranties of Distributor. Distributor hereby represents and warrants to IR-Med that, as of the Effective Date: (a) it has the full corporate right, power, and authority to enter into this Agreement and perform the acts required of it hereunder; (b) its execution and delivery of this Agreement, and its performance of its obligations and duties hereunder, do not and will not violate any agreement to which it is a party or by which it is otherwise bound; and (c) when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with its terms. Any warranty for the Products shall run directly from Distributor to the customer, and pursuant to the warranty the customer shall return any allegedly defective Products to Distributor.

12.2. Representations and Warranties of IR-Med. IR-Med hereby represents and warrants to Distributor that, as of the Effective Date: (a) it has the full corporate right, power, and authority to enter into this Agreement; (b) its execution and delivery of this Agreement, and its performance of its obligations and duties hereunder, do not and will not violate any agreement to which it is a party or by which it is otherwise bound; and (c) when executed and delivered by it, this Agreement will constitute a legal, valid and binding obligation of it, enforceable against it in accordance with its terms. IR-Med shall be responsible to obtain all regulatory authorizations and insurance reimbursements.

12.3. Non-compete. Distributor shall not hire any sales representative or represent, promote or otherwise try to sell any lines or products that, compete with the Products covered by this Agreement. Such non-compete shall survive for a three-year period following termination of this Agreement for any reason.

IR-Med shall not hire any sales representative or represent, promote or otherwise try to sell any lines or products that, compete with the Products covered by this Agreement. Such non-compete shall survive for as long as this Agreement is in force.

12.4 Distributor Undertaking. In the event Distributor receives a bona fide offer for all or part of its business from any third party, during the term of this Agreement, the Distributor shall promptly notify in writing the Company of such offer and include the relevant terms thereof (the "Distributor's Notice"). IR-Med shall have the right of first refusal to purchase the business of the Distributor and shall notify Distributor of its intention to proceed with a due diligence on Distributors' business and eventually match the purchase offer of such third party within fifteen (15) days from the date it receives the Distributor's Notice. The closing of exercise of the Company's option shall be completed not later than 60 days following receipt of the Distributor's Notice. In the event that the Company elects to *not* exercise the option hereunder by written response to the Distributor, then the Distributor shall close the transaction with the intended party within 90 days of the Company's written notice of its determination to *not* exercise the option.

13. Indemnification and Limitation of Liability

13.1. Mutual Indemnity. Each party agrees to indemnify, defend and hold harmless the other party and its officers, directors, employees and agents from and against any and all losses, liabilities, claims, obligations, costs, expenses (including, without limitation, reasonable attorneys' fees) which result from, arise in connection with or are related in any way to claims by third parties arising out of or in connection with (a) the indemnifying party's breach in any material respect of any of such party's obligations representation or warranty under this Agreement; (b) the indemnifying party's gross negligence or willful misconduct in the performance of its obligations under this Agreement; and (c) any violations of applicable laws or regulations by the indemnifying party.

13.2. No Other Liability. NOTWITHSTANDING ANYTHING TO THE CONTRARY HEREIN, NEITHER PARTY NOR ITS AGENT(S), REPRESENTATIVE(S) OR EMPLOYEE(S) SHALL BE LIABLE TO THE OTHER PURSUANT TO THIS AGREEMENT FOR AMOUNTS REPRESENTING LOSS OF REVENUES, LOSS OF PROFITS, LOSS OF BUSINESS OR INDIRECT, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF THE OTHER PARTY, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES..

14. Term; Termination and Effects of Terminations.

14.1. Term. This Agreement will commence on the Effective Date and, unless earlier terminated as herein provided, will remain in force through the thirteenth anniversary of the Commercial Launch Date (the "Term"), ***provided,*** that, if the Distributor is then in compliance with the terms of this Agreement that are applicable to it, then commencing the six (6) months preceding the expiration of each of the third and eight year of the Term, the parties shall enter into good faith negotiations respecting the review and/or re-pricing of the Products as set forth in **Appendix A** and the adjustment of the minimum purchase quantities as set forth in **Appendix B** in light of then prevailing market conditions affecting the Products (hereinafter the "Pricing and Minimum Quantity Terms") with respect to the subsequent five (5) year periods (each being a "Subsequent Period") and conclude such negotiations no later than three (3) months preceding the expiration of each of the third and eight year of the Term respectively. In the event that the Company and the Distributor are not able for whatever reason to reach agreement as to the Pricing and Minimum Quantity Terms for the Subsequent Period, then the Pricing and Minimum Quantity Terms specified in **Appendix B** hereof shall continue in full force and effect with respect to the Subsequent Period. .

Termination for Cause. Either party may immediately cancel this Agreement at any time if the other party breaches any term hereof and fails to cure such breach within ninety (90) calendar days after notice of such breach (if such breach is given to cure) or if the other party shall be or becomes insolvent, or if either party makes an assignment for the benefit of creditors, or if there are instituted by or against either party proceedings in bankruptcy or under any insolvency or similar law or for reorganization, receivership or dissolution. For avoidance of doubt, except as provided in Section 1(iii), (A) failure to make the payment referred in **Appendix A,** (B) comply with the Milestones as described in **Appendix B** or (C) comply with Distributor's undertakings under Section 1 (ii) above, shall constitute a breach of this Agreement if not rectified within ninety (90) days from notice provided by IR-Med.

14.2. Termination by IR-Med Upon Change in Control of Distributor. Notwithstanding the above, in the event of a Change of Control (as defined below) of Distributor, Distributor shall give notice to IR-Med within sixty (60) days before the occurrence of such Change of Control. If such change of control is not accepted by IR-Med, for commercially reasonable basis , IR-Med may terminate the Agreement upon written notice to the Distributor. For the purpose of this Section 14.3 "Change of Control" shall mean:

(i) The acquisition, directly or indirectly, by any individual or legal entity of at least fifty percent (50%) of the voting stock of Distributor or any individual or legal entity that control either party.

(ii) A merger involving Distributor or a party which, directly or indirectly, controls or is controlled by or is under the same control as Distributor. For purposes of this Agreement, "control" meaning the ability to exercise or to procure the exercise, directly or indirectly, of at least fifty percent (50%) of the voting stock of a company.

14.3. If at any time during the term of this Agreement IR-Med or its principal shareholders (i) receive a bona-fide unaffiliated third party offer to purchase the outstanding IR-Med capital shares or the business and all the assets relating to the Product, (ii) such offer is approved and accepted by the Company and its stockholders as required under law (the "Sale Transaction") and (iii) the terms of such Sale Transaction do not include the continuation of this Agreement in accordance with its terms, then the Distributor shall be entitled to **[***]**percent (**[***]**%) of the Net Consideration received by IR-Med or its shareholders, as the case may be.

(A) As used herein, "purchase the outstanding IR-Med capital" –" shall mean

The acquisition, directly or indirectly, by any individual or legal entity of at least fifty percent (50%) of the voting stock of IR-Med.

(B) the consummation of any merger involving the Company in which, immediately after giving effect to such merger, less than a majority of the total voting power of outstanding stock of the surviving or resulting entity is then "beneficially owned" (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934, as amended) in the aggregate by the stockholders of the Company, as applicable, immediately prior to such merger. For the avoidance of doubt and notwithstanding anything herein to the contrary, in no event shall a transaction constitute a "Company Change in Control" if: (w) its sole purpose is to change the state of the Company's incorporation; (x) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction; (y) it is effected primarily for the purpose of financing the Company with cash (as determined by the Board without regard to whether such transaction is effectuated by a merger, equity financing, or otherwise.

(C) As used herein, the term "Net Consideration" shall mean the aggregate consideration received by the Company in respect of the Sale Transaction less any broker fees, professional services fees, or other compensation paid to third parties, taxes and other payments required under law.

D) The Distributor's Share shall be payable on the sixth month anniversary of the closing of the Sale Transaction and only so long as the Distributor and the Purchaser shall not have entered into an agreement for the distribution of the Products.

(E) All determinations and calculation of the foregoing shall be made by the Company. In the event that Distributor disagrees with such determinations, it shall so advise in writing IR-Med no more than fourteen (14) calendar days after its receipt of IR-Med's determinations. The Distributor and IR-Med shall attempt to amicably resolve any such dispute, if within 20 days thereof the matter has not been resolved, the matter will be referred to by an independent accountant (the "Expert") agreed to by the IR-Med and the Distributor and in default of agreement upon such appointment, an Expert appointed by the President of the New York Institute of CPAs, New York county Chapter, upon the request of any Party. The Expert will resolve or settle such matter or dispute in such matter as he/she shall in his/her absolute discretion see fit. The Expert shall be requested to reach his/her decision within thirty (30) days of the matter being referred to him/her. Any decision of the Expert shall be final and binding on the Parties. The cost of the Expert in settling or determining such matter or dispute shall be borne equally by the Parties unless the Expert otherwise determines. Performance of this Agreement shall continue during these proceedings.

15. Miscellaneous.

15.1. Assignment. Except as otherwise provided hereunder with respect to grant of sub-distribution or sub-license rights, Distributor may not assign, delegate, sublicense, pledge, or otherwise transfer any of its rights or obligations under this Agreement without the express written consent of the other party, which consent shall not be unreasonably withheld. Except as set forth in this Section 15, this Agreement will be binding upon and inure to the benefit of the parties hereto, and their employees, officers, directors, partners, and their successors, heirs and assigns.

15.2. Publicity. At its discretion, the Company shall be entitled to issue a press release to the public (and file any required disclosures with the U.S. Securities and Exchange Commission) as to the subject matter of this Agreement and to note in such press release that the Distributor includes persons and other entities who are active in the markets relating to senior care facilities, hospitals, home care centers, and hospital equipment distributors, among others. The press release shall be reviewed by the Distributor.

15.3. Independent Contractors. The relationship of Distributor and IR-Med established by this Agreement is that of independent contractors, and nothing contained in this Agreement will be construed: (a) to give either party the power to direct and control the day-to-day activities of the other; (b) to constitute the parties as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking; or (c) to allow either party to create or assume any obligation on behalf of the other for any purpose whatsoever.

15.4. Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law: (a) such provision shall be excluded from this Agreement; (b) the balance of the Agreement shall be interpreted as if such provision were so excluded; and (c) the balance of the Agreement shall be enforceable in accordance with its terms.

15.5. Force Majeure. In the event performance of this Agreement, or any obligation hereunder, is either directly or indirectly prevented, restricted, or interfered with by reason f fire, flood, earthquake or like acts of God, wars, revolution, civil commotion, explosion, acts of public enemy, embargo, acts of the government in its sovereign capacity, labor difficulties, including without limitation, strikes, slowdowns, picketing, or boycotts, unavailability o f equipment from vendor, changes requested by Customer, or any other circumstances beyond the reasonable control and without the fault or negligence of the Party affected, the Party affected, upon giving prompt notice to the other Party, shall be excused from such performance on a day-to-day basis to the extent of such prevention, restriction, or interference (and the other Party shall likewise be excused from performance of its obligations on a day-to-day basis until the delay, restriction or interference has ceased); provided however, that the Party so affected shall use diligent efforts to avoid or remove such causes of non-performance and both Parties shall proceed whenever such causes are removed or cease. . Any Party claiming a Force Majeure event shall use reasonable diligence to remove the condition that prevents performance and shall not be entitled to suspend performance of its obligations in any greater scope or for any longer duration than is required by the Force Majeure event. Each Party shall use its best efforts to mitigate the effects of such Force Majeure event, remedy its inability to perform, and resume full performance of its obligations hereunder.

15.6. Survival. Sections. 3.13, 7-11 , 12.3 and 15.10 shall survive the termination or expiration of this Agreement.

15.7. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

15.8. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which together shall constitute one instrument.

15.9. Entire Agreement; Enforcement of Rights. This Agreement sets forth the entire agreement and understanding of the parties relating to the subject matter herein all prior discussions between them. No modification, amendment, or any waiver of any rights under this Agreement shall be effective unless in writing signed by the party to be charged. The failure by either party to enforce any rights hereunder shall not be construed as a waiver of any rights of such party.

15.10. Governing Law and Forum. The validity, construction and enforceability of this Agreement shall be governed in all respects by the law of Nevada without reference to conflict of laws principles. With respect to any litigation arising out of or related to this Agreement, the parties agree that it shall be filed in and heard by the state and federal courts with jurisdiction to hear such suits located in New York County, New York. IR-Med and Distributor consent to personal jurisdiction of the state and federal courts of the State of New York and waive any objection to venue in any court located in the State of New York.

15.11. Notices and Other Communications. Notice by any party under this Agreement shall be in writing, addressed to the other party at its respective address given below (or at any such other address as may be communicated to the notifying party in writing), and (a) personally delivered, (b) given by registered mail, (c) delivered by overnight courier, or (d) sent via telecopy confirmed by registered mail, telefax or prepaid cable. Any notice delivered in accordance with this Section 12.8 shall be deemed to have been served when delivered or, if delivery is not accomplished by reason of some fault of the addressee, when tendered:

If to IR-Med:
IR-Med, Inc.
ZHR Industrial Zone, P.O. Box 143,
20 Yahalom St.
Rosh Pinna, 1210002, Israel
Attn: Moshe Gerber, CEO

With copies to David Aboudi

If to Distributor:

PI Prevention Care LLC

[Signature Page to Follow]

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their authorized representatives as of the Effective Date.

I.R Med Ltd.		**PI Prevention Care LLC**	
By:		By:	
Name:		Name:	
Title:		Title:	
Date:		Date:	

APPENDIX A

PRODUCTS

The PressureSafe Solution is comprised of the following:

(i_) *PressureSafe* Device; — 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;

(ii) Disposables –a disposable component, made of plastic polymer and meta, which will be attached to the tip of the device, where the infra-red light source and light collector are located, which are intended to mounted on the PressureSafe scanner tip for taking measurements by direct contact with the human skin

(iii) Software means the current generally available version of the online platform accessible through or for the *PressureSafe* Device and any software from third party licensors included therein , together with any related user manuals and product documentation provided or made available (“Documentation”).. The specific capabilities and functionality of the Software are detailed in the Documentation.

The *PressureSafe* Solution will initially contain a Software component that will provide for the necessary operation and functionality of identifying and addressing latent Pressure Injuries (the “Basic Solution”). From time to time, IR-Med may offer advanced software based options and capabilities, including advanced monitoring of patients, online statistics used in treatment and other functionalities (the “Advanced Solutions”)

The term *PressureSafe* Solution shall include and refer to any upgraded or enhanced version of the *PressureSafe* Solution including, without limitation, any ‘homecare’ version that the Company may then market.

Fees

Licensing Fees

Upon the execution of this Agreement, the Company will be entitled to licensing fee of $**[***]**, of which $**[***]**will be remitted in immediately available cash upon execution of this Agreement and the balance of $**[***]**to be remitted on such date as the Company shall have provided the Distributor with written notice at least at least 90 days prior to the *anticipated* date of the Commercial Launch Date or the NPIAP Guidelines Date as provided in Appendix B below.

Thereafter, commencing on the first anniversary of the completed payment of the initial licensing fee and thereafter on each subsequent anniversary date, an annual licensing fee of $**[***]**and, commencing on the anniversary date following the Insurance Reimbursement Date, the annual licensing fee shall be increased to $**[***]**.

Unit prices

The per unit price the Distributor shall pay to IR- Med shall be a composite amount where the price for each Disposable to the Distributor shall be :**[***]** In addition, if the list price to the customer / user charged by the Distributor for each Disposable exceeds $**[***]** (such excess amount being the “Disposables Price Increase”), then automatically and without any further action, the price to the Distributor shall be increased by an amount equal to **[***]**percent (**[***]**%) of the Disposable Price Increase. By way of illustration, if the Distributor increases the list price to the customer of the Disposable from $**[***]** to $**[***]**, then the price to the Distributor of the Disposables, shall be increased from $**[***]** to $**[***]**. This provision shall apply each and every time that the Distributor shall adjust or change the price per unit payable by the customer and IR-Med’s share of the Disposables Price Increase as herein provided shall be measured from the then base price as to which the Disposables Price Increase was then implemented. The Distributor shall immediately notify in writing IR-Med of any such Disposables Price Increase.

The price of the Software component cannot be determined at the time of the execution of this Agreement and the parties hereby agree that at such time as the Company shall have provided the Distributor with written notice at least at least 90 days prior to the *anticipated* date of the Commercial Launch Date as provided in Appendix B below, the Company and the Distributor shall consult as to the price to be charged to the end user by the Distributor for the Software component (hereinafter the “User Price”) and that the price payable by the Distributor to the Company shall be no less than **[***]**% of the User Price. The parties agree to enter into good faith negotiations to finalize these matters. Notwithstanding the foregoing, the initial price payable by the Distributor to IR-Med for the *PressureSafe* Device shall be $**[***]**and the User Price for such device shall be not less than $**[***]**.

The dollar amounts indicated above and those to be agreed upon in the future by the parties shall be adjusted for inflation during the term of this Agreement at the commencement of every calendar year based on the Consumer Price Index published for the preceding year by the U.S Government.

APPENDIX B

The Distributor shall be solely responsible for the distribution, marketing and sales of the Products in the Territory and shall undertake all commercially reasonable efforts to establish by not later than the Commercial Launch Date (as defined below) a commercially reasonable distribution and sales network for the Products.

Set forth below are the principal components of work plan prepared by the Distributor outlining the Distributor's duties and obligation under the Agreement with respect to the *PressureSafe* device. Each component represents a milestone (each a "Milestone") that is to be satisfied by the Distributor. Upon mutual agreement as reflected in a written instrument signed by both the Company and the Distributor the Milestones below may be adjusted from time to time as circumstances warrant.

I. Distributor Undertakings following Execution of the Agreement and Prior to Commercial Launch

No later than three months following written notice from the Company that all requisite approval for the commercialization of *PressureSafe* have been obtained, Distributor will

1. Open and operate a logistics center in a mutually approved location in the United States to support the distribution, storage and customer support for the PressureSafe devices, disposables, working station units and spare parts.
2. Organize a training center and prepare relevant materials to train the caregivers who are to administer and use the *PressureSafe* device.
3. Technical support center, including "on the phone" technical calling center, technicians that will serve the customers at site within 48 hours from service call.
4. Will prepare all marketing and training materials (printed and digital), manual books, test protocol/steps etc.

Prior to the Commercial Launch Date, the Distributor will invest such resources as is reasonable such that upon the occurrence of the Commercial Launch Date there will be a commercially reasonable distribution network in place for the immediate marketing of the Product. In furtherance thereof, the Company will provide the Distributor with written notice at least 90 days prior to the *anticipated* date of the Commercial Launch Date. Following the Commercial Launch Date and only to the extent necessary for the orderly operation of the distribution efforts, the Distributor will invest an aggregate amount of not less than $**[***]*** during first 12 months following such Commercial Launch Date. The amount invested can be comprised of services and/or other assets.

II. **Distributor Undertakings following Commercial Launch and prior to the *earlier* of Reimbursement Approval or the update by the U.S. National Pressure Injury Advisory Panel (NPIAP) updating its guidelines to recommend the use of technologies and devices such as the Product to be used as a decision support tool for PI checking (each and anyone of these events being a "Market Change").**

From the date of the commercial launch of the PressureSafe (i.e., when the Company determines that all regulatory and other required clearance for product commercialization has been obtained (such date being the "Commercial Launch Date") and until reimbursement approval -

A. By the First anniversary of the Commercial Launch Date - total purchase by Distributor of a minimum of **[***]** PressureSafe devices and **[***]**disposables.

B. By the Second anniversary of the Commercial Launch Date - total purchase by Distributor of a minimum of **[***]** PressureSafe unites and **[***]**disposables.

C. By the Third anniversary of the Commercial Launch Date- total purchase of a minimum of **[***]** PressureSafe devices and **[***]**disposables.

D. From the Fourth anniversary of the Commercial Launch Date through the Fifth anniversary and for each subsequent anniversary thereafter, an increase of a minimum of **[***]**% in sales from the immediately preceding year, ***provided that*** such **[***]**% annual increase in sales in each subsequent year shall be determined by reference to a *base* minimum amount of **[***]** PressureSafe devices and **[***]**disposables at the Fourth anniversary of the Commercial Launch Date, ***plus*** the **[***]**% minimum increase for each subsequent year thereafter

Notwithstanding the foregoing, upon the occurrence of an update by the U.S. National Pressure Injury Advisory Panel (NPIAP) updating its guidelines to recommend the use of technologies and devices such as the Product to be used as a decision support tool for PI checking, then upon notice by the Company to the Distributor and without any further action on the part of any Party, the minimum amounts set forth above shall automatically be increased by **[***]**% effective from the beginning of the "period" following the delivery of such notice.

III. **Distributor Undertakings following Commercial Launch and Reimbursement Approval**

Notwithstanding the foregoing, following reimbursement approval as determined by the Company (such date being the "Reimbursement Approval Date") the above milestones shall be adjusted as follows

A. By the First anniversary of the Reimbursement Approval Dater - total purchase of a minimum of **[***]** PressureSafe devices and **[***]**disposables
B. By the Second anniversary of the Reimbursement Approval Date - total purchase of a minimum of **[***]** PressureSafe devices and **[***]**disposables
C. By the Third anniversary of the Reimbursement Approval Date - total purchase of a minimum of **[***]** PressureSafe devices and **[***]**disposables
D. By the Fourth anniversary of the Reimbursement Approval **[***]** PressureSafe devices and **[***]** disposables,
E. From the Fifth anniversary of the Reimbursement Approval Date through the Sixth anniversary and for each subsequent anniversary thereafter, an increase of a minimum of **[***]**% in sales from the immediately preceding year, ***provided that*** such **[***]**% annual increase in sales in each subsequent year shall be determined by reference to a *base* minimum amount of **[***]**devices and **[***]**disposables at the Fourth anniversary of the Market Change Date, ***plus*** the **[***]**% minimum increase for each subsequent year thereafter.

By way of illustration, between the Fourth and Fifth anniversary of the Market Change Date, the Distributor shall be required to sell a minimum of**[***]** devices (i.e. representing an increase of **[***]**% over the base number of **[***]**devices) and *** disposables (i.e. representing an increase of **[***]**% over the base number of **[***]** disposables); between the Sixth and Seventh anniversary of the Market Change Date, the Distributor shall be required to sell a minimum of **[***]** units (i.e. representing an increase of **[***]**% over the immediately preceding year minimum) and **[***]** (i.e. representing an increase of **[***]**% over the immediately preceding year minimum).

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In all cases above, at the Distributor's option, in any year the Distributor may vary the number of *PressureSafe* devices and the Disposables that it is required to purchase from the Company such that in such year the dollar value to the Company of the purchases of devices and disposables as so varied by the Distributor is equal to the total dollar value specified above at the then prevailing prices. By way of illustration, in year one following the Commercial Launch and Reimbursement Approval, the Distributor is required to purchase from the Company a minimum of **[***]** P*ressureSafe* devices and **[***]**disposables at a price payable to the Company of $**[***]**per device and $***per disposable for a total dollar value payable to the Company in such year of $**[***]**. The Distributor can vary the number of devices and disposable required to be purchased in such year so long as Distributor purchases and pays into the Company at least $**[***]**in respect of the purchase of devices and disposables.

APPENDIX C

Purchase Order Procedure, and Payment Terms

No later than 90 days before the beginning of each term year and upon written notice from the Company to the Distributor to that effect, the Distributor shall deliver to the Company a binding Purchase Order (PO) for the Distributor's purchase minimum (or more) of the applicable Product amounts set forth in **Appendix B** for the entire term year. The Company will deliver to the Distributor 25% of the order quantity by the middle of each quarter. Failure to deliver such PO on time will result in loss of exclusivity.

a) In case of the first term year, the Distributor shall issue a binding PO within 30 days after the Commercial Launch Date, and this PO will be for the full quantity of the year and the Company shall use commercially reasonable efforts to deliver at least 50% of the entire PO within 4 months of the PO, and the balance within 6 months of the PO.

b) In case of a Market Change as defined in Appendix B (FDA Approval or a Change in NPIAP Guidelines), the Distributor will issue an updated PO within 30 days of the Market Change date.

c) The Distributor may issue additional PO's during the term year, and in such case shall include a quantity of a multiplier of **[***]** devices and/or a multiplier of **[***]**disposables. The PO's items shall be delivered within 3 months of the PO.

2) Payment terms: The Company will invoice the Distributor per each quantity shipped to the Distributor. The Distributor shall pay the Invoice at NET 30 days of the invoice.

3) The Distributor will carry the shipment costs of the delivered orders from the Company to the Distributor.

If for whatever reason the Company is unable to fill the Product Purchase Order submitted by the Distributor before the term year for that year's minimum purchase requirements as herein provided, then the time period with respect to the minimum purchase requirement specified above shall be tolled for the period in which the Company was unable to fulfill the Product Purchase Order and the minimum purchase requirements shall be reinstated as herein provided above immediately following the time that the Company resumes fulfilling the Product Purchase Orders

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
OF REGISTRANT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002
(RULE 13a-14(a) or 15d-14(a) OF THE EXCHANGE ACT)

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: November 14, 2022

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
OF REGISTRANT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002
(RULE 13a-14(a) or 15d-14(a) OF THE EXCHANGE ACT)

I, Sharon Levkoviz, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IR-Med, Inc..;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's Board of Directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

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

Date: November 14, 2022

EXHIBIT 32.1

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

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 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: November 14, 2022

EXHIBIT 32.2

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

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the quarterly period ended September 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: November 14, 2022